

# EXHIBIT B

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESAL PRICE	)	
LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
	)	
<b>THIS DOCUMENT RELATES TO:</b>	)	Hon. Patti Saris
	)	
<i>United States of America, ex rel. Ven-a-Care</i>	)	
<i>of the Florida Keys, Inc. v. Abbott</i>	)	
<i>Laboratories, Inc., CIVIL ACTION NO. 06-</i>	)	
<i>11337-PBS</i>	)	

**UNITED STATES' OBJECTIONS AND RESPONSES TO ABBOTT LABORATORIES,  
INC.'S REVISED FIRST SET OF REQUESTS FOR ADMISSION TO PLAINTIFF  
UNITED STATES OF AMERICA AND RELATOR VEN-A-CARE OF THE FLORIDA  
KEYS, INC.**

Plaintiff, United States of America (“United States” or “Plaintiff”), pursuant to Rule 36 of the Federal Rules of Civil Procedure, hereby serves its objections and responses to Defendant Abbott Laboratories, Inc.’s ("Abbott") Revised First Set of Requests for Admission to Plaintiff United States and Relator Ven-A-Care of the Florida Keys, Inc. (“Relator” or “Ven-A-Care”) ("Abbott's RFAs") The United States incorporates by reference and reasserts all objections and responses to the Definitions and Instructions contained in Defendant Abbott Laboratories, Inc.'s First Set of Requests for the Production of Documents and Tangible Things to Plaintiff United States of America and Defendant Abbott Laboratories Inc.'s First Set of Requests for the Production of Documents and Tangible Things to Relator Ven-A-Care of the Florida Keys, Inc.

**Additional General Objections:**

Plaintiff further objects to Abbott's RFAs on the following grounds:

- a. Abbott's RFAs exceed the total number of RFAs set forth in the Case Management order, which authorized 150 non-authentication RFAs in total and 100 authentication RFAs. In contravention to Rule 36's requirement that "each matter of which an admission is requested shall be separately set forth," Abbott attempts to improperly circumvent the numerical Requests for Admission limitations set forth in the Court's Case Management Order ("CMO") by combining several requests into one request in Abbott's RFAs numbered 1 through 69.
- b. Abbott's RFAs numbered 1 through 69 are improper authentication RFAs, which do not properly seek information concerning the genuineness of a document described in the request.
- c. Many of Abbott's RFAs reference documents that were not served in their entirety to Abbott's RFAs, in contravention to the Rule 36 requirement that they be served with the request.
- d. Abbott's definition of Average Whole Sale Price or AWP is incorporated by reference from its First Set of Requests for the Production of Documents and Tangible Things to Plaintiff United States of America and its First Set of Requests for the Production of Documents and Tangible Things to Relator Ven-A-Care of the Florida Keys, Inc., and defines Average

Whole Sale Price or AWP as having the meaning "ascribed" in paragraphs 44 and 50 of the original Complaint filed by the United States. However, this purported definition is nonsensical as Paragraphs 44 and 50 of the Complaint on their face do not define AWP, which thereby renders Abbott's definition of AWP for purposes of Abbott's RFAs meaningless. If Abbott were trying to define AWP as a price published by Pricing Compendia, that approach would not be consistent with the term as set forth in *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 460 F.Supp.2d 277 (D. Mass. 2006)("the Court construes the statutory term according to its plain meaning and holds that AWP means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies"). AWP is given its plain meaning definition, as explained in further detail at pp. 15-19 of the United States' Amicus Curiae Brief, filed in *In Re: Pharmaceutical Industry Average Wholesale Price Litigation*, Case No. 1:01-cv-12257-PBS, Document 3104-1. When responding and objecting herein, and for all other purposes with respect to Abbott's RFAs, the United States refers to AWP as having its plain language meaning as set forth in the United States' Amicus Curiae Brief. Abbott requests that the United States' responses to Abbott's RFAs be "under oath," which is improper. Rule 36 does not require that responses to Requests for Admission be made under oath; indeed, Rule 36 was specifically amended to remove such a requirement. Accordingly, the following responses and objections by the United States are not made under oath.

## **Requests for Admission**

### **Requests for Admission Seeking Authentication Of Documents**

1. On August 6, 1968, Irwin Wolkstein, Assistant Director of the Division of Policy and Standards at the U.S. Department of Health, Education and Welfare, wrote a memorandum stating that the "Red book" is a "listing of prices of manufacturers which is often violated by volume and other discounts" and "would be subject to abuse by manufacturers setting prices high to advantage retailers." Exhibit 1 is a true and accurate copy of that memorandum. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the memorandum, and was made and kept in the course of regularly conducted business activity.

#### **OBJECTION TO RFA #1:**

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and improperly quotes Exhibit "1" by taking the selected language out of context. The United States states that Exhibit "1" speaks for itself, in the entirety of the document referenced in RFA #1. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "1", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, it would be unduly burdensome to the United States to research and determine whether the memorandum attached as Exhibit "1" was made by a person with knowledge of the contents of the memorandum, when it was made given that it was a memorandum that is 39 years old and wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "1", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #1:**

Subject to the above objections, with respect to the sentences 1, 2 and 3 of RFA #1, the United States admits with qualification that Irwin Wolkstein, who at the time was the Assistant Director of the Division of Policy, was the listed author of a memorandum dated August 6, 1968.

A true and correct copy of the memorandum attached as Exhibit "1" was maintained in the ordinary course of regularly conducted business of the U.S. Department of Health, Education and Welfare and speaks for itself. The quoted language in Sentence 1 of the RFA is out of context and incomplete. The United States admits that entire the sentence contained as the last sentence of the second paragraph in Exhibit "1" incorporating some of the RFA #1 quoted language is as follows: "A proposed alternative acquisition cost basis is the Red book – a listing of prices of manufacturers which is often violated by volume and other discounts to which would be subject to abuse by manufacturers setting prices high to advantage retailers." Qualifying further, Exhibit 1 speaks for itself and the events of this time frame are immaterial.

Subject to the above objections, the United States further admits with qualification that Exhibit "1" is a true and correct copy of the administrative confidential memorandum to addresses Joseph A. Higgins, Drug Task Force; Donald Rucker, ORS; Robert M. Smith, OPEP, dated August 6, 1968 addressed from Irwin Wolkstein, Assistant Director of Division of Policy Standards. By making the qualified admissions herein concerning the content of Exhibit "1", however, the United States does not admit that the words or statements contained in Exhibit "1" represent any position by Centers for Medicare and Medicaid Services ("CMS"), or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "1".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**2. In December 1968, a Task Force of the U.S. Department of Health, Education and Welfare published a background paper on payment for prescription drugs, which stated, among other things: "The Red Book and Blue Book do not reflect the actual manufacturers' prices to wholesalers and retailers, which are determined by the amounts of various kinds of discounts." Exhibit 2 is a true and accurate copy of that background paper. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

## **OBJECTION TO RFA #2:**

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and improperly quotes Exhibit "2", taking the selected language out of context. The United States objects to and denies any request that it admit the truthfulness of the language misquoted from Exhibit "2", and states that Exhibit "2" speaks for itself in its entirety.

Objecting further, this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "2", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial. This request is also objectionable on the grounds that Abbott failed to attach a true and correct copy of the complete document referenced in Exhibit "2", rendering Abbott's authentication impossible to respond to.

Objecting further, it would be unduly burdensome to the United States to research and determine whether the memorandum was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the document or its time period beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "2", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

## **RESPONSE TO RFA #2:**

Subject to the above objections, the United States admits with qualification only that in December of 1968, a Task Force of the United States Department of Health, Education and Welfare published a background paper entitled "The Drug Makers and the Drug Distributors". A true and correct copy of only 10 select pages of the 70-plus page background report attached as Exhibit 2, but the United States denies that Exhibit "2" is a true and correct copy of that background paper. Qualifying further, Exhibit "2" speaks for itself and the events of this time frame are immaterial. The complete background report was maintained in the ordinary course of regularly conducted business of the U.S. Department of Health, Education and Welfare. The quoted language in Sentence 1 of this RFA is out of context and incomplete. The United States admits only that the entire sentence contained on page 31 of the report, column 2, second complete sentence, December 1968 Task Force background paper is as follows: "However, Red Book and Blue Book do not reflect the actual manufacturers' prices to wholesalers and retailers, which are determined by the amounts of various kinds of discounts." By making the qualified admissions herein concerning the content of Exhibit "2", however, the United States does not admit that the words or statements contained in Exhibit "2" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "2".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**3. Exhibit 3 is a true and correct copy of a brief filed on or about January 12, 1990 by the Department of Health and Human Services in the United States Court of Appeals for the Fifth Circuit in The State of Louisiana v. The United States Department of Health and Human Services, Case No. 89-4566 (5th Cir., July 13, 1990). It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the record, and was made and kept in the course of regularly conducted business activity.**

### **OBJECTION TO RFA #3:**

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "3" speaks for itself, in the entirety of the document referenced in RFA #3. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "3", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

With respect to sentence 2 of RFA #3, it would be unduly burdensome to the United States to research and determine whether the memorandum was "made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the record." Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "3", the United States will not challenge such an introduction on authenticity or genuineness grounds. Exhibit "3" is a public document that speaks for itself, except that the first page of the document was improperly retyped by Jones Day, counsel for the Defendant. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

### **RESPONSE TO RFA #3:**

Without waiving the above objections, the United States admits with qualification that, with the exception of the first page that was retyped by Defendant's counsel, Exhibit 3 is a true and correct copy of a brief filed on or about January 12, 1990 by the Department of Health and Human Services in the United States Court of Appeals for the Fifth Circuit in The State of Louisiana v. The United States Department of Health and Human Services, Case No. 89-4566. Qualifying further, Exhibit 3 speaks for itself and the events of this time frame are immaterial.

Without waiving the above objection, the United States admits with qualification subject



to the above objections, that Exhibit "3" is a public document that was maintained in the ordinary course of the business of the United States Department of Health and Human Services. By making the qualified admissions herein concerning the content of Exhibit "3", however, the United States does not admit that the words or statements contained in Exhibit "3" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**4. In November 1974, HCFA issued a draft regulation calling for states to pay the lesser of a federally-set MAC or EAC plus a dispensing fee to Providers dispensing Medicaid-covered drugs. 39 Fed. Reg. 41,480 (Nov. 27, 1974). In that draft regulation, HCFA expressly rejected AWP as the benchmark for reimbursement because AWP's "are frequently in excess of actual acquisition cost to the retail pharmacist." Exhibit 4 is a true and accurate copy of that regulation. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #4:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 4 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and improperly quotes Exhibit "4" by taking the selected language out of context. The United States states that Exhibit "4" speaks for itself, in the entirety of the document referenced in RFA #4. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "4".

Objecting further, it would be unduly burdensome to the United States to research and determine whether the proposed rule making was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the record. With respect to sentence 4 of RFA #4, it would be unduly burdensome to the United States to research and determine whether the proposed rule attached as Exhibit "4" was made by a person with knowledge of the contents of the proposed rule making. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott

elect to attempt to introduce a true, complete and correct copy of Exhibit "4", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy. The United States states that Exhibit "4" speaks for itself in its entirety.

#### **RESPONSE TO RFA #4:**

Subject to the above objections, the United States admits with qualification only that in November of 1974, the Department of Health Education and Welfare issued proposed rule making, a copy of which is attached as Exhibit 4. This public document speaks for itself. The United States denies that portion of sentence 2 of RFA #4 stating that "[i]n that draft regulation, HCFA expressly rejected AWP as the benchmark for reimbursement because AWPs". As stated, the quoted language comes from proposed rule making and does not constitute a formal position by HCFA.

The quoted language in Sentence 2 of this RFA is out of context and misquotes at least one word. The United States admits only that the November of 1974 proposed rule making provides, in part, at p. 41-180, column 2, "Acquisition Costs: In referring to drug cost, current regulations specify "costs as determined by the State." Most states use average wholesale price, Red Book data, Blue Book data, survey results or similar standard costs. Such standard prices are frequently in excess of actual acquisition costs to the retail pharmacist. Thus, to achieve maximum savings to the Medicaid program, the proposal requires the use of actual acquisition cost." By making the qualified admissions herein concerning the content of Exhibit "4", however, the United States does not admit that the words or statements contained in Exhibit "4" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "4" and that the attached represents a true and correct copy of the document containing that quoted language. Qualifying further, Exhibit 4 speaks for itself and the events of this time frame are immaterial.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**5. Commenting on the final regulation setting Medicaid reimbursement in July 1975, HCFA stated that "published wholesale prices often are not closely related to the drug prices actually charged to, and paid by, providers." 40 Fed. Reg. 32,293 (July 31, 1975). Exhibit 5 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

**OBJECTION TO RFA #5:**

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and improperly quotes Exhibit "5" by taking the selected language out of context. Exhibit "5" is also an illegible copy, and objectionable for that reason alone. The United States states that Exhibit "5" speaks for itself, in the entirety of the document referenced in RFA #5. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "5".

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "5", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy. The United States states that Exhibit "5" speaks for itself in its entirety.

**RESPONSE TO RFA #5:**

Subject to the above objections, the United States admits with qualification only that in the July 1975 document is a public document speaks for itself that contains the language quoted in RFA #5, in the context that it appears in the document. The United States admits that Exhibit 5 is a true and accurate, but illegible copy of 40 Fed. Ref. 32, 293 (July 31, 1975), that was created at or near the time, by or from information transmitted by, a person with knowledge of its contents and kept in the ordinary course of the business of HCFA. Qualifying further, Exhibit "5" speaks for itself and the events of this time frame are immaterial.

By making the qualified admissions herein concerning the content of Exhibit "5", however, the United States does not admit that the words or statements contained in Exhibit "5" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "5" and that the attached represents a true and correct copy of the document containing that quoted language.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**6. In December 1977, HCFA issued a memorandum to state Medicaid agencies that stated: "The Department is not convinced that those states which continue to reimburse at [AWP] . . . have made a real effort to approach [actual acquisition cost]." HCFA Action Transmittal 77-113 (MMB) (Dec. 13, 1977). Exhibit 6 is a true and accurate copy of that memorandum. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #6:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and misquotes Exhibit "6" by taking the selected language out of context. The United States states that Exhibit "6" speaks for itself, in the entirety of the document referenced in RFA #6. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "6", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, it would be unduly burdensome to the United States to research and determine whether the memorandum attached as Exhibit "6" was made by a person with knowledge of the contents of the memorandum, when it was made given that it was a memorandum that is 31 years old and wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "6", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #6:**

Subject to the above objections, with respect to the first, second and third sentences of RFA #6, the United States admits that a true and correct copy of the memorandum attached as Exhibit 6 was maintained in the ordinary course of regularly conducted business of the U.S. Department of Health, Education and Welfare. Exhibit "6" speaks for itself and the events of this time frame are immaterial. The quoted language in Sentence 1 of RFA #6 is out of context and incomplete.

The United States admits that the entire sentence contained as the last sentence of the third paragraph, second sentence of the Text of Transmittal in Exhibit "6" incorporating some of the RFA #6 quoted language is as follows: "However, the Department is not convinced that those states which continue to reimburse at average wholesale price (AWP), or wholesale invoice cost, have made a real effort to approach AAC [actual acquisition cost]".

Subject to the above objections, the United States further admits with qualification that Exhibit "6" is a true and correct copy of the Medicare and Medicaid Guide ¶ 28,714. By making the qualified admissions herein concerning the content of Exhibit "6", however, the United States does not admit that the words or statements contained in Exhibit "6" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003. Rather the United States acknowledges only that the quoted language is contained in Exhibit "6" and that the attached represents a true and correct copy of the document containing that quoted language.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**7. Exhibit 7 is a true and accurate copy of Department of Health and Human Services, Departmental Appeals Board, Decision No. 1273 (Aug. 22, 1991), which states: "An audit conducted in 1983 by the HHS Office of the Inspector General (OIG) in six states (including Arkansas) found that pharmacists' drug costs averaged about 16% below the AWP, and that in only 14 of 3,469 purchases examined did providers pay the AWP or higher (and then for extenuating reasons)." This decision was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #7:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 2 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and quotes Exhibit "7" by taking the selected language out of context. Objecting further, Exhibit "7" speaks for itself, in the entirety of the document referenced in RFA # 7. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "7", including without limitation, its completeness, its relevance, its hearsay content, its

prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, it would be unduly burdensome to the United States to research and determine whether the memorandum attached as Exhibit "7" was made by a person with knowledge of the contents of the memorandum, when it was made given that it was a 1991 memorandum that quotes language that is now more than 24 years old and irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "7", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #7:**

Subject to the above objections, with respect to the first sentence of RFA #7, the United States admits with qualification only that a true and correct copy of the August 22, 1991 decision of the Department of Health and Human Services Departmental Appeal Board Docket No. 90-119 is attached as Exhibit 7 and was maintained in the ordinary course of regularly conducted business of the U.S. Department of Health, Education and Welfare. Qualifying further, Exhibit 7 speaks for itself and the events of this time frame are immaterial. The quoted language in Sentence 1 of RFA #7 is out of context and incomplete. The United States admits that entire the third paragraph on page 3, Section B drug pricing, of Exhibit "7" incorporates the RFA #7 quoted language as follows: "An audit conducted in 1983 by the HHS Office of the Inspector General (OIG) in six states (including Arkansas) found that pharmacists' drug costs averaged about 16% below the AWP, and that in only 14 of 3,469 purchases examined did providers pay the AWP or higher (and then for extenuating reasons). (HCFA Exhibit (EX.)F, p. 4)".

By making the qualified admissions herein concerning the content of Exhibit "7", however, the United States does not admit that the words or statements contained in Exhibit "7" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003. Rather the United States acknowledges only that the quoted language is contained in Exhibit "7" and that it represents a true and correct copy of the portion of that document containing the language.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**8. In June 1984, HHS-OIG published a report of its audit of pharmacy drug purchases in six states, titled "Changes to the Medicaid Prescription Program Could Save Millions" (the "June 1984 HHS-OIG Audit Report"), which found that 99.6**



**percent of the 3,469 pharmacy purchases audited were made at prices averaging approximately 15.93 percent below AWP, as a result of purchase and trade discounts that were routinely available to purchasing pharmacies. Exhibit 8 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #8:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. This RFA characterizes Exhibit "8" by taking the paraphrasing language out of context. The United States states that Exhibit "8" speaks for itself, in the entirety of the document referenced in RFA # 8. The United States further objects on the grounds that this request seeks information from September of 1984 that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the paraphrased document attached as Exhibit "8", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, it would be unduly burdensome to the United States to research and determine whether the memorandum attached as Exhibit "8" was made by a person with knowledge of the contents of the memorandum, when it was made given that it was a 1984 document and wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "8", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #8:**

Subject to the above objections, the sentences comprising RFA #8 are admitted in part, subject to the qualification that the United States admits only to the exact content of the language of that report, which is as follows, as found at ¶ 34,157, 10,197, paragraph one, under the heading Providers' Drug Ingredient Costs Are Much Lower Than AWP: "Although most of the program expenditures for prescription drugs are based on the use of published AWP as upper reimbursement limits, our review showed that pharmacies rarely purchased drugs at AWP. In

fact, of the 3,469 drug purchases that were examined in the six states, only 14 purchases were made at AWP or greater. These 14 purchases were generally made only because of extenuating circumstances, such as special "fill-in" orders where discounts were not given because only one item was purchased. Most of the purchases – 3,455 (99.6 percent) – were made at prices averaging 15.93 percent below AWP. These drug purchases ranged from as little as 0.23 percent below AWP to as much as 41.78 percent below AWP. The range of discounts by state are shown in the following tables [tables omitted], but paraphrased herein as conveying low and high AWP rates for Arkansas, Colorado, Massachusetts, Michigan, North Carolina and Oregon as ranging from a low of 0.45 [Arkansas to a high of 40.54 (Arkansas)]. It should be noted that only those purchase and trade discounts that could be identified to a specific drug price were considered. We were not able to readily determine other types of quantity, cumulative quantity, or year-end rebates and discounts which pharmacies may have received. Therefore, it is possible that the pharmacies' actual drug costs may have been lower than the discounted invoice prices." The United States admits that Exhibit "8" is a true and correct copy of a portion of ¶ 34,157 Medicaid - Limitation on Payment for Drugs, Medicare and Medicaid Guide from September of 1984 that contains the language quoted above. Qualifying further, Exhibit "8" speaks for itself and the events of this time frame are immaterial.

By making the qualified admissions herein concerning the content of Exhibit "8", however, the United States does not admit that the words or statements contained in Exhibit "8" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "8".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**9. HCFA informed all state Medicaid agencies in a Medicaid Action Transmittal dated September 1984 (No. 84-12) that "[w]ithin the pharmaceutical industry, AWP means undiscounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price. . . . Excessive payments are being made nationwide for the ingredient cost of prescription drugs under the Medicaid program. The purpose of this report is to alert Department management to the opportunity for significant reductions in program expenditures if actions are taken to stop the present widespread use of [AWP] in determining program reimbursement for prescription drugs." Exhibit 9 is a true and accurate copy of that transmittal letter. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**



**OBJECTION TO RFA #9:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. This RFA characterizes Exhibit "9" by taking the quoted language out of context, and indeed, impermissibly cutting and pasting selected quotes of language that is out of order as it appears in the document. The United States states that Exhibit "9" speaks for itself, in the entirety of the document referenced in RFA #9. The United States further objects on the grounds that this request seeks information from September of 1984 that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "9", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial. This request is, in part, objectionable still further to the extent that it seeks information duplicative of that sought in RFA #8 above. The United States reasserts its objections, qualifications and responses to RFA #8 herein. Objecting further, it would be unduly burdensome to the United States to research and determine whether the memorandum attached as Exhibit "9" was made by a person with knowledge of the contents of the memorandum, when it was made given that it was a 1984 document and wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "9", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

**RESPONSE TO RFA #9:**

Subject to the above objections, the sentences comprising RFA #9 are admitted in part, subject to the qualification that the United States admits only the exact content of the language of that report in the order that the language appears, which is as follows, as found at ¶ 34,157, 10,192, paragraph one, under the heading OVERVIEW OF THE PROBLEM AND IMPROVEMENTS NEEDED: "Excessive payments are being made nationwide for the ingredient cost of prescription drugs under the Medicaid program. The purpose of this report is to alert Departmental management officials to the opportunity for significant reductions in program expenditures if actions are taken to stop the present widespread use of (AWP) in determining program reimbursement for prescription drugs. Currently, most states use AWP as an upper reimbursement limit for drugs – approximately 80 percent, or about \$1.3 billion, of the total annual Medicaid drug expenditures (\$1.7 billion) are reimbursed with AWP serving as the

upper reimbursement limit. Within the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price." Qualifying further, Exhibit "9" speaks for itself and the events of this time frame are immaterial.

The United States qualifies that the term AWP as set forth in the quoted language above as the pharmaceutical industry's definition is not the true and accurate definition of AWP. Rather, AWP is accurately defined by statute. The United States admits that Exhibit "9" is a true and correct copy of the portion of ¶ 34,157 Medicaid - Limitation on Payment for Drugs, Medicare and Medicaid Guide from September of 1984 that contains the language quoted above.

By making the qualified admissions herein concerning the content of Exhibit "9", however, the United States does not admit that the words or statements contained in Exhibit "9" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "9".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**10. In a 1986 survey report on Hawaii's Medicaid Program, HCFA Region IX stated that HHS (then known as HEW) "believed that published [AWPs], which were being used as a major pricing reference for reimbursement of prescription drugs in the Medicaid program, were not representative of the prices pharmacists paid for drugs." HHS also stated in this report that "[i]t is apparent from this review that AWP, which is the basis for the State's EAC, is not a reliable predictor of the prices pharmacists actually pay for drugs." The report further stated that the survey showed that "pharmacies generally purchase drugs at prices that are discounted significantly below AWP" and that "AWPs are not determined by surveying market transactions and thus do not accurately reflect prices pharmacists pay for drug products." Exhibit 10 is a true and accurate copy of that survey report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #10:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 5 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an

improper request seeking information concerning the genuineness of the document; and quotes Exhibit "10" by taking the selected language out of context. Notably, the quoted language is taken from a number of different pages of this multi-page document, and spliced together improperly. The quoted language is objectionable as presented as it is taken out of context and out of order as it appears in the document. The United States states that Exhibit "10" speaks for itself, in the entirety of the document referenced in RFA #10. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "10", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, it would be unduly burdensome to the United States to research and determine whether the memorandum attached as Exhibit "10" was made by a person with knowledge of the contents of the memorandum, when it was made given that it was a 1986 document and wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "10", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #10:**

Subject to the above objections, the United States admits with qualification only that the language quoted in RFA #10 is contained in Exhibit 10, but it is quoted out of context and out of order as it appears in the document, which pertains only to the Hawaii Medicaid program. Specifically, the "believed that published [AWPs], which were being used as a major pricing reference for reimbursement of prescription drugs in the Medicaid program, were not representative of the prices pharmacists paid for drugs" is contained on page 1, paragraph 2 of the Introduction and Background section of the document. The language "[i]t is apparent from this review that AWP, which is the basis for the State's EAC, is not a reliable predictor of the prices pharmacists actually pay for drugs" is contained on page 6, paragraph 1 of the conclusion section of the document. The language "pharmacies generally purchase drugs at prices that are discounted significantly below AWP" and that "AWPs are not determined by surveying market transactions and thus do not accurately reflect prices pharmacists pay for drug products" is contained in the first full paragraph on page 2 of the document.

The United States admits that Exhibit "10" is a true and correct copy of March 3, 1986 EAC survey conducted in Hawaii in the FY 86 by Region IX, concerning the Hawaii Medicaid program. Qualifying further, Exhibit "10" speaks for itself and the events of this time frame are immaterial.

By making the qualified admissions herein concerning the content of Exhibit "10", however, the United States does not admit that the words or statements contained in Exhibit "10" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "10".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**11. In a speech given on Sept. 28, 1987 at the Symposium on the New Medicaid Regulations on Drug Reimbursement, Robert Helms, Ph.D., Assistant Secretary for Planning and Evaluation at HHS, stated, among other things, that a 1982 Task Force appointed by Secretary Schweiker identified the "clear unworkability of the MAC process," "arbitrary and unfair results," and the "artificiality" of "Red Book prices." Exhibit 11 (HHC902-1078 through HHC902-1089) is a true and accurate copy of Mr. Helms' remarks. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the remarks, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #11:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning a purported speech from 1987 without providing an accurate and complete transcript of that speech, and by seeking the authentication of a document that on its face reflects that it is a draft document. The United States asserts that Exhibit "11" speaks for itself, in the entirety of the document referenced in RFA #11. Moreover, the United States objects to this request on the grounds that the quotations from the draft document are taken out of context of that document. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "11", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, it would be unduly burdensome to the United States to research and determine the exact content of a speech purportedly delivered in 1987 without a transcript of that speech. Further, it would be unduly burdensome for the United States to research and determine whether the draft document attached as Exhibit "11" was made by a person with knowledge of

the contents of the memorandum, when it was made given that it was a 1991 memorandum that quotes language that is 20 years old and wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003.

#### **RESPONSE TO RFA #11:**

Subject to the above objections, the United States denies with qualification sentences 2 and 3 as the document attached as Exhibit "11" on its face purports to be a draft and is not a transcript of a speech. The United States admits that the language quoted in RFA #11 is contained in Exhibit 11, but is quoted out of context and out of order as it appears in the document. The correct quotation of the language is, as set forth in context on Page 3 of Exhibit "11" continued paragraph 1: "Some of the problems we identified were: the clear unworkability of the MAC process; arbitrary and unfair results, such as the use of very low generic prices for products which were not in fact widely available at those prices; disruption of regular purchasing channels; and, artificiality of both Red Book prices for some products and dispensing fee surveys."

The United States can neither admit nor deny the exact content of the speech purportedly delivered by Robert B. Helms, Ph.D. without an accurate and complete transcript of that speech. It would be unduly burdensome to expect the United States to recreate in 2008 such a transcript of a 1987 speech. Qualifying further, Exhibit "11" speaks for itself and the events of this time frame are immaterial.

By making the qualification herein concerning the content of Exhibit "11", however, the United States does not admit that the words or statements contained in Exhibit "11" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "11".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**12. On April 26, 1988, HCFA's Region VI chief state operations officer, Don Hearn, in a letter to the Office the Director, Bureau of Eligibility, Reimbursement and Coverage, stated: "It has been repeatedly shown that AWP is an inflated figure and does not comply with [statutory requirements] that Medicaid payments be consistent with efficiency, economy, and quality of care. We also believe that use of the AWP cannot meet the definition of EAC found at CFR 447.301, i.e. the 'agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers.'" Exhibit 12 (HHC011-0861 through HHC001-0862) is a true and accurate copy of that letter. It was made at or near the**



**time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #12:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and quotes Exhibit "12" by taking the selected language out of context. The United States states that Exhibit "12" speaks for itself, in the entirety of the document referenced in RFA # "12". The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "12", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, it would be unduly burdensome to the United States to research and determine whether the memorandum attached as Exhibit "12" was made by a person with knowledge of the contents of the memorandum, when it was made given that it was a 1988 document and wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "12", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #12:**

Subject to the above objections, the United States admits with qualification only that the language quoted in RFA #12 is contained in Exhibit "12", but it is quoted out of context and pertains the Oklahoma Medicaid Program. The correct quote from page 1, paragraph 3 of the April 26, 1988 document is as follows:

"It has been repeatedly shown that AWP is an inflated figure and does not comply with Section 1902(a)(30) of the Social Security Act and 42 CFR 447.200 which require that Medicaid payments be consistent with efficiency, economy, and quality of care. We also believe that use of the AWP cannot meet the definition of EAC found at CFR 447.301, i.e. the 'agency's best

estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers." Qualifying further, Exhibit "12" speaks for itself and the events of this time frame are immaterial.

The United States admits that Exhibit "12" is a true and correct copy of April 26, 1988 letter from Don Hearn, Chief State Operations Branch recommending disapproval of amendment no. 87-18 of the Oklahoma Medicaid State Plan.

By making the qualified admissions herein concerning the content of Exhibit "12", however, the United States does not admit that the words or statements contained in Exhibit "12" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "12".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**13. On or about May 16, 1988, the HCFA Administrator stated in a letter disapproving Louisiana's State Plan Amendment No. 87-33: "We believe there is a preponderance of evidence that demonstrates that AWP significantly overstates the price that pharmacy providers actually pay for drug products and, thus, is not 'the price generally and currently paid by providers.' The continued use of AWP results in significant potential overpayments to pharmacy providers." Exhibit 13 is a true and accurate copy of that letter. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #13:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and quotes Exhibit "13" by taking the selected language out of context. The United States states that Exhibit "13" speaks for itself, in the entirety of the document referenced in RFA # "13". The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "13", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon

how it is presented at trial.

Objecting further, it would be unduly burdensome to the United States to research and determine whether the memorandum attached as Exhibit "13" was made by a person with knowledge of the contents of the memorandum, when it was made given that it was a 1988 letter and wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "13", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

### **RESPONSE TO RFA #13:**

Subject to the above objections, the United States admits with qualification only that the language quoted in RFA #13 is contained in Exhibit 13, but it is quoted out of context and incomplete. The correct quote from page 1, paragraph 2 of the May 12, 1988 document is as follows:

"We believe that there is a preponderance of evidence that demonstrates that AWP significantly overstates the price that pharmacy providers actually pay for drug products and, thus, is not the 'price generally and currently paid by providers.' The continued use of AWP results in significant potential overpayments to pharmacy providers".

The United States admits that Exhibit "13" is a true and correct copy of May 12, 1988 letter from William L. Roper, M.S. Administrator, to the Louisiana Office of Family Security.

By making the qualified admissions herein concerning the content of Exhibit "13", however, the United States does not admit that the words or statements contained in Exhibit "13" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "13". Qualifying further, Exhibit 13 speaks for itself and the events of this time frame are immaterial.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**14. On August 12, 1988, HCFA's Regional Administrator, J.D. Sconce, informed U.S. Senator Dale Bumpers in a letter that "[t]here is a preponderance of evidence that demonstrates that the published AWP significantly overstates the price that pharmacy providers actually pay for drug products and, thus, is not 'the price generally and currently paid by providers.'" Exhibit 14 (HCC011-2189 through**



**HHC001-2190) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #14:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and quotes Exhibit "14" by taking the selected language out of context. The United States asserts that Exhibit "14" speaks for itself, in the entirety of the document referenced in RFA # "14". The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "14", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, it would be unduly burdensome to the United States to research and determine whether the memorandum attached as Exhibit "14" was made by a person with knowledge of the contents of the memorandum, when it was made given that it was a 1988 letter and wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "14", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #14:**

Subject to the above objections, the United States admits only with qualification that the language quoted in RFA #14 is contained in Exhibit 14, but it is quoted out of context and incomplete. The quoted language only correctly quotes sentence two from page 1, paragraph 3 of the August 12, 1988 document. The United States admits that Exhibit "14" is a true and correct copy of August 12, 1988 letter from William L. Roper, M.S. Administrator, to the Louisiana Office of Family Security.

By making the qualified admissions herein concerning the content of Exhibit "14",

however, the United States does not admit that the words or statements contained in Exhibit "14" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "14". Qualifying further, Exhibit 14 speaks for itself and the events of this time frame are immaterial.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**15. On September 22, 1988, HCFA's Program Analysis Officer, Peter Rodler, testified under oath as follows: "In early November 1983, the Secretary of [HHS] appointed a, I believe, four member task force to conduct public hearings to obtain comments from concerned individuals as to ways in which the current Medicaid drug regulations could improve. It was a three day session in which I was present and the executive's secretary of the National Wholesale Druggist Association, which is the professional association of wholesalers that sell drugs nationwide, testified that AWP is like the sticker price on an automobile. It is the very highest price that anyone would be expected to pay for the drug product. I remember that statement very clearly. Obviously I spent twelve years in reimbursement policy for the Medicaid program, and that statement has significant meaning." Exhibit 15 contains a true and accurate copy of that testimony. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #15:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "15", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, without questioning the stenographer, it would be unduly burdensome to the United States to research and determine whether the transcript portion attached as Exhibit "15" was made by a person with knowledge of the contents of the transcript, when it was made given that transcript pertains to 1988 testimony that is wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "15", the United States will not challenge such an introduction on

authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #15:**

Subject to the above objections, sentences 1 and 2 of RFA # 15 are admitted with the following qualifications. Exhibit "15" speaks for itself and the events of this time frame are immaterial. The United States does not admit that the words or statements contained in Exhibit "15" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in the small portion transcript of the speech given by Mr. Rodler attached as Exhibit "15". The entire lengthy transcript is not contained in Exhibit "15".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**16. Also on September 22, 1988, HCFA's Region VI Medical Policy Specialist, Nancy Saltzman, testified under oath as follows: "I don't think anyone has ever disputed the fact – or to my knowledge that I've spoken with, has ever disputed the fact that discounts are there. I think there is – some people believe that those discounts are not available under certain circumstances, such as you have to buy "X" number of dollars to receive those or you have to pay your bills on time or what have you. There are various types of discounts, and we found that before and we found that again. The OIG found the same thing. But they're always there and I will not say always available, but if a provider meets the criteria – let me put it this way, there are things, discounts that we call routine discounts, and to us, that means those discounts are always available to the pharmacists. They're trade discounts, as Mr. Rodler testified earlier. The wholesalers do not consider AWP to be the price that is paid by pharmacists routinely to purchase drug products. There are instances, we have been told, where a provider may actually pay AWP. I have had one or two providers tell me they'll pay AWP if they have to go down the street and buy it from another provider, that product from another provider. If they need it today or overnight and they can't get it from their primary wholesaler or manufacturer, whoever they buy it from, they may get it from a secondary source that they don't do business with all the time or very much dollar business with, and they may be charged and pay the AWP. But again, I would say, guessing, probably ninety to ninety-five percent of the purchases are made at prices below the AWP, and that's confirmed by what the wholesalers tell us. Interviews with wholesalers, interview with pharmacists, in prior years, in current years." Exhibit 16 contains a true and accurate copy of that testimony. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

**OBJECTION TO RFA #16:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "16", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, without questioning the stenographer, it would be unduly burdensome to the United States to research and determine whether the transcript portion attached as Exhibit "16" was made by a person with knowledge of the contents of the memorandum, when it was made given that transcript pertains to September 1988 testimony that is wholly irrelevant to this case, which concerns the time period of Abbott conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "16", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy. Exhibit 16 represents a portion of the same transcript identified in Exhibit 15. The United States hereby incorporates all objections to Exhibit 15 as if fully set forth herein.

**RESPONSE TO RFA #16:**

Subject to the above objections, sentences 1 and 2 of RFA # 16 are admitted with the following qualifications only. Exhibit "9" speaks for itself and the events of this time frame are immaterial.

By making the qualified admissions herein concerning the content of Exhibit "16", however, the United States does not admit that the words or statements contained in Exhibit "16" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in the small portion transcript of the speech given by Ms. Salzman attached as Exhibit "16", which speaks for itself. The entire lengthy transcript is not contained in Exhibits "15" or "16".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**17. In July 1989, HCFA's Associate Regional Director for Region IX , Lawrence L. McDonough, stated as follows in a letter to the Deputy Director of California's**

**Department of Health Services, John Rodriguez: "While we can understand that the term 'average wholesale price' connotes what pharmacies pay for drug products, in the pharmaceutical industry it is commonly understood to be higher than actual costs. There have been a number of studies which indicate that the published AWP overstates actual prices paid by as much as 10-25 percent because of discounts, premiums, special offers or incentives." Exhibit 17 (HHC016-0747 through HHC016-0748) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #17:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and quotes Exhibit "17" by taking the selected language out of context. The United States states that Exhibit "17" speaks for itself, in the entirety of the document referenced in RFA #17. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "17", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, it would be unduly burdensome to the United States to research and determine whether the memorandum attached as Exhibit "17" was made by a person with knowledge of the contents of the letter, when it was made given that it was a 1989 letter and wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "17", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #17:**

Subject to the above objections, the United States admits with qualification only that the language quoted in RFA #17 is contained in Exhibit 17, but it is quoted out of context and

incomplete. The correct language contained in the second sentence of the fourth paragraph, page 1 of Exhibit 17 is: "While we can understand that the term 'average wholesale price' connotes what pharmacies pay for drug products, in the pharmaceutical industry it is commonly understood to be higher than actual costs. There have been a number of studies which indicate that the published AWP overstates actual prices paid by as much as 10-20 percent because of discounts, premiums, special offers or incentives." Qualifying further, Exhibit 17 speaks for itself and the events of this time frame are immaterial.

The United States admits that Exhibit "17" is a true and correct copy of July 1989 letter to John Rodriguez, Deputy Director, Medical Care Services, Department of Health Services.

By making the qualified admissions herein concerning the content of Exhibit "17", however, the United States does not admit that the words or statements contained in Exhibit "17" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in Exhibit "17".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**18. HCFA's Acting Administrator, Louis B. Hays, testified before the Senate Special Committee on Aging in 1989 that "[w]hile the term 'average wholesale price' is suggestive of the amount that pharmacies actually pay for the drugs, it is in fact significantly higher than actual costs. The average wholesale price is somewhat comparable to the manufacturer's sticker price on a new car." Mr. Hays' prepared written statement adds: "this is rarely the price actually paid for the car." Exhibit 18 is a true and accurate copy of this testimony. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #18:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 4 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "18", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, without questioning the stenographer, it would be unduly burdensome to the United States to research and determine whether the transcript portion of the Senate



Special Committee testimony attached as Exhibit "18" was made by a person with knowledge of the contents of the memorandum, when it was made given that transcript pertains to July 1989 testimony that is wholly irrelevant to this case, which concerns the time period of Abbott conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "18", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #18:**

Subject to the above objections, sentences 1, 2 and 3 of RFA # 18 are admitted with the following qualifications. Exhibit 18 speaks for itself and the events of this time frame are immaterial. By making the qualified admissions herein concerning the content of Exhibit "18", however, the United States does not admit that the words or statements contained in Exhibit "18" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in the small portion transcript of the remarks speech given by Mr. Hays attached as Exhibit "18".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**19. In 1989, the Senate Special Committee on Aging issued a report stating that AWP exceeds actual drug prices, that the Department of Veteran's Affairs received an average discount of 41% off of AWP for single source drugs and an average of 67% off of AWP for multiple source sources, and that hospitals, HMOs, and nursing homes that contract with wholesalers achieve discounts up to 99% off AWP. Majority Staff Report, Special Committee of Aging, United States Senate, "Prescription Drug Prices: Are We Getting Our Money's Worth?," S. Rep. 101-49 at 11 (1989). Exhibit 19 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #19:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 4 Requests for Admission and, in part as a

result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States asserts at this time and reserves all objections to the admissibility of the referenced document attached as Exhibit "19", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, it would be unduly burdensome to the United States to research and determine whether the transcript portion of the Senate Report testimony attached as Exhibit "19" was made by a person with knowledge of the contents of the memorandum, when it was made given that transcript pertains to a September 1989 Report that is wholly irrelevant to this case, which concerns the time period of Abbott conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "19", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #19:**

Subject to the above objections, sentences 1, 2 and 3 of RFA # 19 are admitted with qualification only that exact quotations of the paraphrased language contained in RFA #19 is at page 11: "DVA achieves an average discount of 41% off the manufacturer's published "Average Wholesale Price" (AWP) for single source drugs (those still under patent), and an average of 67% off the published AWP for multiple source drugs. . . . Hospitals, Health Maintenance Organizations, and nursing homes that contract with wholesalers to purchase prescription drugs from a predetermined list are able to achieve discounts of up to 99% of the manufacturer's published "Average Wholesale Price" (AWP), even for brand name products. . ." Qualifying further, Exhibit 19 speaks for itself and the events of this time frame are immaterial.

By making the qualified admissions herein concerning the content of Exhibit "19", however, the United States does not admit that the words or statements contained in Exhibit "19" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in the portion of the Senate Special Committee on Aging attached as Exhibit "19".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**20. On or around July 31, 1989, Senator David Pryor (D-Ark) made statements in the U.S. Senate about Medicare reimbursement for drugs. Among other things, Senator Pryor commented: "After all the charts and all the graphs and all the**



words, it comes down to this: for the same bottle of prescription drugs, different buyers pay dramatically different prices. For example, if we look at the price of the brand-name painkiller 'Motrin,' the published list price is \$32. If the new Medicare prescription drug benefit were currently in place, Medicare would pay \$29. Mr. President, the Veterans' Administration has been smart. They have gone and dealt with drug manufacturers. They say, 'We want a better price.' The bottom line is that the Veterans' Administration pays a price of \$5 for a bottle of capsules of Motrin. Medicare pays \$29 for the same bottle." 135 Cong. Rec. 9059 (daily ed. July 31, 1989) (statement of Sen. Pryor). Exhibit 20 is a true and accurate copy of that testimony. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

#### **OBJECTION TO RFA #20:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 4 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "20", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, without questioning the stenographer, it would be unduly burdensome to the United States to research and determine whether the transcript portion Sen. Pryor's comments attached as Exhibit "20" was made by a person with knowledge of the contents of the memorandum, when it was made given that transcript pertains to July 1989 commentary testimony that is wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "20", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #20:**

Subject to the above objections, sentences 1, 2 and 3 of RFA # 20 are admitted with qualification. Exhibit "20" speaks for itself and the events of this time frame are immaterial. By making the qualified admissions herein concerning the content of Exhibit "20", however, the United States does not admit that the words or statements contained in Exhibit "20" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of

this case from 1991 until 2003, but rather the United States acknowledges only that the quoted language is contained in the attached as Exhibit "20".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**21. In October 1989, the HHS-OIG issued a report on Medicaid reimbursement that stated: "[W]e continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare Programs." Use of Average Wholesale Price in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program (A-06-89-00037) (Oct. 1989). Exhibit 21 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #21:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and quotes Exhibit "21" by taking the selected language out of context. The United States states that Exhibit "21" speaks for itself, in the entirety of the document referenced in RFA # "21". The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "21", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, this 1989 report is wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "21", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

**RESPONSE TO RFA #21:**

Subject to the above objections, the United States admits sentences 2 and 3 of RFA #21 with qualification. With respect to sentence 1 of RFA #21, the complete quoted sentence is as follows: "Based on our work then and our current ongoing efforts, we continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare Programs." Qualifying further, Exhibit "21" speaks for itself and the events of this time frame are immaterial.

By making the qualified admissions herein concerning the content of Exhibit "21", however, the United States does not admit that the words or statements contained in Exhibit "21" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**22. Relying on the October 1989 HHS-OIG Report, HCFA REVISED its State Medicaid Manual to instruct State Medicaid agencies not to use AWP as a drug's EAC for Medicaid reimbursement purposes "without a significant discount being applied." HCFA, State Medicaid Manual § 6305.1. Exhibit 22 is a true and accurate copy of that provision of the HCFA State Medicaid Manual. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

**OBJECTION TO RFA #22:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and quotes Exhibit "22" by taking the selected language out of context. The United States states that Exhibit "22" speaks for itself, in the entirety of the document referenced in RFA # "22". The United States further objects on the grounds that this request, or portions thereof, seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "22", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, this 1989 Medicaid Manual is wholly irrelevant to this case, which concerns the time period of Abbott conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "22", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

#### **RESPONSE TO RFA #22:**

Subject to the above objections, the United States admits sentences 2 and 3 of RFA #22 with qualification. With respect to sentence 1 of RFA 22, partial admission that the complete paraphrased sentence is as follows: "Consequently, without valid documentation to the contrary, a published AWP level as a State determination of EAC without a significant discount being applied is not an acceptable estimate of prices generally and currently paid by providers." Pursuant to Exhibit 22, this conclusion in the Medicaid Manual was predicated not upon the OIG report, but rather upon a number of unidentified studies. The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein. Qualifying further, Exhibit "22" speaks for itself and the events of this time frame are immaterial.

By making the qualified admissions herein concerning the content of Exhibit "22", however, the United States does not admit that the words or statements contained in Exhibit "22" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**23. On October 5, 1989, HCFA informed the Arkansas Department of Health Services in a letter: "The published AWP is not an acceptable measure because it is frequently inflated and does not reflect the various incentives, sales promotions, discounts and allowances (other than discounts for cash or prompt payment) that are routine terms of purchasing in the drug marketplace." Exhibit 23 (HHC010-0969 through HHC010-0970) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #23:**

As noted in the General Objections, the United States objects to Abbott's definition of

AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and quotes Exhibit "23" by taking the selected language out of context. Objecting further, Exhibit "23" speaks for itself in the entirety of the document. The United States further objects on the grounds that this request, or portions thereof, seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "23", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial. The United States asserts at this time and reserves all objections to the admissibility of the referenced document attached as Exhibit "23", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, this 1989 document is wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "23", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

### **RESPONSE TO RFA #23:**

Subject to the above objections, admitted with qualification that events of 1989 are immaterial to this case. Qualifying further, Exhibit 23 speaks for itself and the events of this time frame are immaterial.

By making the qualified admissions herein concerning the content of Exhibit "23", however, the United States does not admit that the words or statements contained in Exhibit "23" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**24. In 1990, Secretary of HHS Louis Sullivan testified before Congress: "Many studies and most information available on this subject show that the list prices for**

**drug products—commonly known as Average Wholesale Price (AWP)—rarely, if ever, reflect the prices pharmacies actually pay . . . . Since 1976, our policy has been that AWP is not an acceptable measure of EAC." Medicaid Prescription Drug Pricing: Hearing on S. 2605 and S. 3029 Before the Senate Committee on Finance, 101st Cong. 308-310 (1990). Exhibit 24 is a true and accurate copy of that testimony. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #24:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document; and quotes Exhibit "24" by taking the selected language out of context. The United States states that Exhibit "24" speaks for itself, in the entirety of the document referenced in RFA #24. The United States further objects on the grounds that this request, or portions thereof, seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "24", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial. The United States asserts at this time and reserves all objections to the admissibility of the referenced document attached as Exhibit "24", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

Objecting further, this 1990 transcript document is wholly irrelevant to this case, which concerns the time period of Abbott conduct beginning in 1991 and extending through to 2003. Without questioning the stenographer, it would be unduly burdensome to the United States to research and determine whether the transcript portion of the testimony attached as Exhibit "23" was made by a person with knowledge of the contents of the memorandum, when it was made given that transcript pertains to 1990 testimony that is wholly irrelevant to this case, which concerns the time period of Abbott conduct beginning in 1991 and extending through to 2003. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "24", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.



#### **RESPONSE TO RFA #24:**

Subject to the above objections, admitted with qualification, Exhibit "24" speaks for itself and the events of this time frame are immaterial. By making the qualified admissions herein concerning the content of Exhibit "24", however, the United States does not admit that the words or statements contained in Exhibit "24" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**25. On May 8, 1990, Senator Pryor made the following statement in the United States Senate: "There are two domestic markets in the U.S. for most big-selling prescription drugs: a price-competitive market, characterized by deep discounts off the published list price (benefiting the Department of Veterans Affairs, hospitals, and managed care plans, such as HMOs), and a high-priced market where retail customers, Medicare, and Medicaid purchase their prescription drugs." He further commented that the Department of Veterans Affairs "achieves an average discount of 41% off the manufacturer's published 'Average Wholesale Price' (AWP) for single source drugs and an average of over 60% off the AWP for multiple source drugs. In contrast, Medicaid programs, in almost all cases, pay top dollar (or at best, AWP minus 10%) for drug products." 136 Cong. Rec. E5814 (daily ed. May 8, 1990) (statement of Sen. Pryor). Exhibit 25 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #25:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning the stenographer, it would be unduly burdensome to the United States to research and determine whether the Senate record transcript attached as Exhibit "25" was made by a person with knowledge of the contents of the memorandum, when it was made given that transcript pertains to 1990 testimony that is wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003. Qualifying further, Exhibit "25" speaks for itself and the events of this time frame are immaterial.

Without waiving the foregoing and any other objection that the United States has to this

document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "25", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 5 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "25" is a public document that speaks for itself, in the entirety of the document referenced in RFA #25. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "25", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #25:**

Subject to the above objections, admitted as to sentences 1, 2 and 3 with qualification that events of 1990 are immaterial to this case.

By making the qualified admissions herein concerning the content of Exhibit "25", however, the United States does not admit that the words or statements contained in Exhibit "25" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**26. On May 10, 1990, Senator David Pryor (D-Ark) made the following statement in the U.S. Senate: "I have brought with me today two medicine bottles that illustrate the shameful situation we must correct. I would ask my colleagues to note that these two bottles are the same. They're the same because they contain the same quantity of the same drug to treat serious stomach ulcers--a drug called Zantac--and because they were both made by the same brand name manufacturer. But one of these bottles was purchased by the Veteran's Administration for \$34, while the other was purchased by the Medicaid program for \$68. An anti-asthma medication made by Schering-Plough that is sold to the Veterans' Administration for \$8 while an identical package of the drug commands three times as much--\$24--from the fiscally struggling Medicaid Program. And I could just as easily have brought in bottles of the very popular anti-hypertensive drug called**



**Dyazide. For 2 years now, the Veteran's Administration has negotiated a price of \$50 for a 1,000 capsules, but Medicaid pays about \$280 for the same package from the same company. Mr. President, as talented as the negotiators at the Veterans' Affairs are, they aren't the only people getting access to good prices for prescription drugs. Besides the vast majority of hospitals and HMO's in this country, other industrialized nations of the world are getting much better deals as well." 136 Cong. Rec. S5986 (daily ed. May 10, 1990) (statement of Sen. Pryor). Exhibit 26 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #26:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning the stenographer, it would be unduly burdensome to the United States to research and determine whether the Senate record transcript attached as Exhibit "26" was made by a person with knowledge of the contents of the memorandum, when it was made given that transcript pertains to 1990 testimony that is wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "26", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "26" is a public document that speaks for itself, in the entirety of the document referenced in RFA #26. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "26", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #26:**

Subject to the above objections, admitted as to sentences 1 and 2 with qualification. The

quoted language in Sentence 1 of this RFA is taken out of context and omits an intervening sentence after the phrase “anti-hypertensive drug called Dyaside.” but before the sentence beginning “For two years now, the Veterans’ Administration . . .” Moreover, qualifying further, Exhibit “26” speaks for itself and the events of this time frame are immaterial.

By making the qualified admissions herein concerning the content of Exhibit "26", however, the United States does not admit that the words or statements contained in Exhibit "26" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**27. In July 1990, HCFA's M. J. Christenberry, Associate Regional (Region VI) Administrator, Division of Medicare, sent a memo to HCFA's Kathleen Buto, Director, Bureau of Policy Development that stated: "We believe it is time to revise Medicare's drug payment policy for several reasons." One of the reasons cited was that "[p]rices in the Red Book are inflated and do not represent physicians' and suppliers' acquisition costs" and that Red Book prices "are ‘well above the prices at which supplier can purchase these factors' and ‘substantial discounts are available'." Exhibit 27 (HHC906-0093 through HHC906-0098) is a true and accurate copy of that memo. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #27:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "27", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy. Objecting further, this 1990 memo is wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003.

The United States objects to this request on the grounds that it contains 4 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the

document. The United States states that Exhibit "27" is a public document that speaks for itself, in the entirety of the document referenced in RFA #27. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "27", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #27:**

Subject to the above objections, admitted as to sentences 1, 2 and 3 with qualification. The quoted language in sentence 1 of this RFA is taken out of context and omits several intervening paragraphs in between the quoted phrases contained in sentence 1. Qualifying further, Exhibit 27 speaks for itself and the events of this time frame are immaterial.

By making the qualified admissions herein concerning the content of Exhibit "27", however, the United States does not admit that the words or statements contained in Exhibit "27" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA

**28. On or around September 12, 1990, Congressmen Ron Wyden (D-Or.) and Jim Cooper (D-Tenn.) introduced a bill in U.S. House of Representatives titled the "Medicaid Prescription Drug Fair Access and Pricing Act of 1990." In extension of remarks made in the Congressional Record, Representative Wyden stated: "Medicaid isn't getting competitive prices because Medicaid has never required competitive prices." He also stated that the VA paid an average of 41 percent less for drugs than the Medicaid Program, and displayed charts comparing VA prices and Medicaid reimbursement. For single source drugs, the charts showed an example where Medicaid paid 93% more than the Federal Government. For multi-source drugs, the chart showed percentage differences of 1130% and 5000%. 136 Cong. Rec. E2813 (daily ed. Sept. 12, 1990) (statement of Rep. Wyden). Exhibit 28 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #28:**

As noted in the General Objections, the United States objects to Abbott's definition of

AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning the stenographer, it would be unduly burdensome to the United States to research and determine whether the Congressional Record transcript attached as Exhibit "28" was made by a person with knowledge of the contents of the transcript, when it was made given that transcript pertains to 1990 proposed legislation that is wholly irrelevant to this case, which concerns the time period of Abbott's conduct beginning in 1991 and extending through to 2003.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "28", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 5 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States asserts that Exhibit "28" speaks for itself, in the entirety of the document referenced in RFA #28. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States reserves all objections to the admissibility of the document attached as Exhibit "28", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

## **RESPONSE TO RFA #28:**

Subject to the above objections, the United States denies that the quoted language is contained is misquoted by only selectively quoting certain language out of context from Exhibit 28. Specifically the following phrase "Medicaid isn't getting competitive prices because Medicaid has never required competitive prices." is incomplete and misleading. The complete sentence ends in the phrase "from drug companies as a condition of reimbursement." The United States denies the subjective characterization paraphrasing of RFA #28. Qualifying further, Exhibit "28" speaks for itself and the events of this time frame are immaterial.

By making the qualified admissions herein concerning the content of Exhibit "28", however, the United States does not admit that the words or statements contained in Exhibit "28" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**29. HHS' Appeals Board stated as follows in a decision on August 22, 1991: "In the mid-1970's, HCFA had proposed to limit payment to actual acquisition costs, apparently to counter the practice of using the AWP in national drug pricing publications. Determining actual costs was burdensome, however, and the agency ultimately decided to specify use of estimate costs in its regulations." Department of Health and Human Services, Departmental Appeals Board, Decision No. 1273 (Aug. 22, 1991). Exhibit 29 is a true and accurate copy of that decision. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #29:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "29", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "29" is a public document that speaks for itself, in the entirety of the document referenced in RFA #29. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "29", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #29:**

Subject to the above objections, admitted with qualification. The proper quoted phrase incorporates the term "estimated" not "estimate". Qualifying further, Exhibit 29 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "29", however, the United States does not admit that the words or statements contained in Exhibit "29" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**30. On August 12, 1992, HCFA's Associate Regional Administrator for Region X, Albert J. Benz, wrote a memo stating: "[B]ecause of variations in carrier calculation methodologies, there is the potential for carriers to derive different AWP amounts from the same data. The carriers in this region have informed us that these calculations are tremendously time consuming. One carrier estimated that over a month of staff time was required to perform this task. The present practice of each carrier calculating the AWP independently is duplicative, prone to errors and variances in payment amounts and extremely expensive. If the costs to all the carriers are considered, they would run into the tens of thousands of dollars" (emphasis in original). Exhibit 30 (HHC903-0976 through HHC903-0977) is a true and accurate copy of that memorandum. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the memorandum, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #30:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "30", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "30" is a public document that speaks for itself, in the entirety of the document referenced in RFA #30. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "30", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.



### **RESPONSE TO RFA #30:**

Subject to the above objections, admitted with the qualification that Exhibit 30 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "30", however, the United States does not admit that the words or statements contained in Exhibit "30" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**31. An HHS-OIG report dated November 6, 1992, titled Physicians' Costs for Chemotherapy Drugs (A-01-91-01049), stated that "[H]igh dollar volume chemotherapy drugs are available at a cost below AWP. For example, one of the five providers submitted a claim for drugs administered on March 7, 1991. Analysis showed that each drug's cost was below AWP and that the total cost for the drugs claimed was 48% of AWP." Exhibit 31 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

### **OBJECTION TO RFA #31:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "31", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "31" is a public document that speaks for itself, in the entirety of the document referenced in RFA #31. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "31",

including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #31:**

Subject to the above objections, admitted with the qualification that RFA #31 misquotes Exhibit 31 by selectively quoting language mid-sentence and mid-paragraph. The complete quotation is of the cited paragraph: " In addition, misconceptions among physicians about AWP and cost contributed to complaints about Medicare reimbursements for chemotherapy drugs. For example: \* a physician stated he thought that only large institutions can obtain drugs at prices as low as AWP; \*several physicians advised that discounts offered to small practitioners for drugs usually pertain only to goods with a limited life (short date); and, a carrier, based on input from physicians, represented that discounts below AWP usually apply on to multiple-source drugs. Our analysis disproved these misconceptions and established that high dollar volume chemotherapy drugs are available at a cost below AWP. For example, one of the five providers submitted a claim for drugs administered on March 7, 1991. Analysis showed that each drug's cost was below AWP and that the total cost for the drugs claimed was 48% of AWP." Qualifying further, Exhibit 31 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "31", however, the United States does not admit that the words or statements contained in Exhibit "31" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**32. An HHS-OIG report dated October 20, 1992, titled Cost of Dialysis-Related Drugs (A-01-91-00526), included a chart on p.6 showing that based on surveys of actual invoice prices at 30 dialysis facilities during May 1991, the EAC of Vancocin/Vancomycin 500 ML was \$5.00 and the median AWP for the same drug was \$19.17. Exhibit 32 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #32:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "32", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "32" is a public document that speaks for itself, in the entirety of the document referenced in RFA #32. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "32", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #32:**

Subject to the above objections, admitted with the qualification that the RFA #32 paraphrases page 6 of Exhibit 32, which speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "32", however, the United States does not admit that the words or statements contained in Exhibit "32" represent any position by CMS or HHS OIG, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, but rather Exhibit 32 on its face reflects that it is only communicating draft information and recommendations to the Action Administrator of HCFA.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**33. A 1993 GAO report, which studied drug acquisition cost and Medicaid reimbursement in Maryland and Illinois, found that Medicaid reimbursement exceeded drug acquisition cost by 10-23% in Illinois, and by 11-34% in Maryland. Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland, GAO Report (HRD-93-55FS) (Mar. 18, 1993). Exhibit 33 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

### **OBJECTION TO RFA #33:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning the GAO employee responsible for its typographic transcription, it would be unduly burdensome to the United States to research and determine whether the transcript portion of the GAO attached as Exhibit "33" was made by a person with knowledge of the contents of the report.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "33", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "33" is a public document that speaks for itself, in the entirety of the document referenced in RFA #33. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "33", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

### **RESPONSE TO RFA #33:**

Subject to the above objections, admitted, in part, with the qualification that the RFA #33 paraphrases Exhibit 33, which speaks for itself. The United States denies that the statistical information cited in RFA #33 pertains to any reimbursement other than the 9 pharmacies in Illinois and Maryland referenced on the face of Exhibit 33 at page 4. Denying this RFA in part, the United States further submits that Exhibit #33 does not appear to account for or report the spreads of more than 100 to 2000% on the Subject Drugs sold by the 9 pharmacies at issue in the report, which spread information Abbott concealed from the United States.

By making the qualified admissions herein concerning the content of Exhibit "33", however, the United States does not admit that the words or statements of the GAO report contained in Exhibit "33" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any

other admission or qualification concerning the subject matter of this exhibit or RFA.

**34. In a memorandum dated November 2, 1993, the Director of the Medicare Carrier Operations Branch for Region X, Fred Rosen, stated to Carol Walton, Director, Bureau of Program Operations: "We believe that the area of drug pricing continues to be an area where there are huge carrier fee discrepancies for the same products. Medicare carriers have great latitude in establishing drug pricing since Medicare regulations are broad and HCPC coding does not fully reflect various drug concentrations, dosages and packages." He also stated that the "continued use of Drug Topics Redbook or Medispan, as the source for AWP data is still a problem, since AWP data reported in these publications, by all accounts, is greatly inflated." Exhibit 34 (HHC019-0291 through HHC019-0292) is a true and accurate copy of that memorandum. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the memorandum, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #34:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "34", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 4 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "34" is a public document that speaks for itself, in the entirety of the document referenced in RFA #34. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "34", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #34:**

Subject to the above objections, admitted with the qualification that the selectively quoted

language in RFA #34 is taken out of context. Exhibit 34 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "34", however, the United States does not admit that the words or statements contained in Exhibit "34" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**35. A letter addressed to all Region IV Medicare Carriers and dated May 25, 1994 stated: "In accordance with 42 CFR 405.517, carriers may, but are not required to, take into account overhead costs such as inventory and spoilage, in determining the EAC. This could be determined based on actual cost surveys or other means. For example, a carrier might determine that an overhead allowance of 10 percent above the material costs would be equitable in establishing the EAC." Exhibit 35 (AWP057-0832 through AWP057-0833) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the memorandum, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #35:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context. Further, the document attached as Exhibit #35 appears to be incomplete and it is impossible to ascertain its authorship, whether it was actually a letter sent to anyone, or whether it is a draft.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "35", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "35" is a public document that speaks for itself, in the entirety of the document referenced in RFA #35. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this



time and reserves all objections to the admissibility of the document attached as Exhibit "35", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #35:**

Subject to the above objections, the United States admits only that the quoted language is contained in Exhibit "35" of this incomplete document. Exhibit 35 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "35", however, the United States does not admit that the words or statements contained in Exhibit "35" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**36. On October 17, 1994, the Chief of the Medicare Technical Issues Section, Frank J. Camozzi, wrote a letter to Susan Coonfield, Manager of Medicare Claim Administration at Aetna Life Insurance Company, that stated: "In July [1994], because of a protest under the Reduction of Paperwork Act, the Office of Management and Budget asked that we suspend the surveys being conducted to arrive at an estimated acquisition cost. Thus, at this time, all carrier drug pricing is based on the AWP." Exhibit 36 (HHC015-1677 through HHC015-1679) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #36:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "36", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on

the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "36" is a public document that speaks for itself, in the entirety of the document referenced in RFA #36. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "36", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #36:**

Subject to the above objections, admitted with the qualification that the quoted language is taken out of context and Abbott's then or former counsel, Hogan & Hartson, openly participated in a concerted lobbying effort to seek the suspension of the survey initiative, which was not the choice of DHS. Qualifying further, Exhibit 36 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "36", however, the United States does not admit that the words or statements contained in Exhibit "36" represent any other position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, except as set forth on the face of Exhibit 36.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**37. On February 2, 1995, the Chief of the Medicare Technical Issues Section, Frank J. Camozzi, wrote a letter to Celeste Brose, Supervisor, Focused Medical Review, Blue Shield of California, that stated: "Drugs are [paid] at the lowest of the national Average Wholesale Price (AWP), Estimated Acquisition Cost (EAC) or actual charge. As no method for arriving at the EAC has been approved, drugs are priced at AWP." Exhibit 37 (HHC015-1618) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #37:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and

correct copy of Exhibit "37", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "37" is a public document that speaks for itself, in the entirety of the document referenced in RFA #37. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "33", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #37:**

Subject to the above objections, admitted with the qualification that the quoted language from Exhibit 37 was quoted out of context. Exhibit 37 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "37", however, the United States does not admit that the words or statements contained in Exhibit "37" represent any further position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, except as reflected on the face of Exhibit "37".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**38. A February 26, 1996 Barron's Magazine article stated: "Much of the revenues of an oncology practice, and often most of the profits come from hefty markups of the prices of cancer drugs. These drug mark ups which can be 60% or more, are a ready target for HMOs and the federal government's increasingly strapped Health Care financing agency." The article also stated: "The big bills for cancer treatment start with the manufacturers who can set high wholesale prices for chemo drugs because there is little competition," "but oncologists tack on their own profit margin when they bill for drugs. Anecdotes abound about the size of mark ups and their importance to the profits at oncology practices." Painful Profits: Cancer Treatment Firms May Soon See Plump Margins Slashed, Barron's Magazine (Feb. 26, 1996). Exhibit 38 is a true and accurate copy of that article. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly**

**conducted business activity.**

**OBJECTION TO RFA #38:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning the editors or typesetters of Barron's magazine, it would be unduly burdensome to the United States to research and determine whether the transcript portion of the testimony attached as Exhibit "38" was made by a person with knowledge of the contents of the article. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "38", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 4 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of a published periodical article. The United States states that Exhibit "38" is a public document that speaks for itself, in the entirety of the document referenced in RFA #38. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "38", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

**RESPONSE TO RFA #38:**

Subject to the above objections, the United States admits only that the language quoted in RFA #38 appears in Exhibit #38 concerning cancer drugs, not the Subject drugs. The United States submits that the quoted language is taken out of context. Moreover, the term "financing agency" is erroneously misquoted in form as it is not capitalized, and the term "there is" appears as "there's" in Exhibit #38, which speaks for itself. The United States cannot be expected to research and provide any further admissions concerning the publication of this periodical article concerning drugs.

By making the qualified admissions herein concerning the content of Exhibit "38", however, the United States does not admit that the words or statements contained in Exhibit "38" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**39. A June 10, 1996 Barron's Magazine article stated: "For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60-90% below the so-called average wholesale price, or AWP, used in reimbursement claims." Hooked on Drugs: Why Do Manufacturers Pay Such Outrageous Prices For Pharmaceuticals?, Barron's Magazine (June 10, 1996). Exhibit 39 is a true and accurate copy of that article. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #39:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning the editors or typesetters of Barron's magazine, it would be unduly burdensome to the United States to research and determine whether the transcript portion of the testimony attached as Exhibit "39" was made by a person with knowledge of the contents of the article. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "39", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "39" is a public document that speaks for itself, in the entirety of the document referenced in RFA #39. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "39", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

### **RESPONSE TO RFA #39:**

Subject to the above objections, the United States admits only that the language quoted in RFA #39 appears in Exhibit #39. The United States submits that the quoted language is taken out of context and qualifies that Exhibit #39 speaks for itself. The United States cannot be expected to research and provide any further admissions concerning the publication of this periodical article concerning drugs.

By making the qualified admissions herein concerning the content of Exhibit "39", however, the United States does not admit that the words or statements contained in Exhibit "39" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**40. On August 5, 1996, Dr. Grant E. Steffen of CMS wrote a letter to Jill Merrill, Medicare Program, HCFA (Denver, Colorado), that stated: "Is it not possible for HCFA and the OMB to collaborate on a set of questions that would constitute a valid survey of acquisition costs? Today I received Ms. Debus' letter stating that a RIL dated August 12, 1996 [sic] requested that this carrier suspend any effort to survey physicians for AC. Until today, I was not aware of this RIL. Two years have passed and there has been no visible attempt at collaborating on a valid survey. Perhaps such a collaboration is more difficult than I can imagine, or perhaps this is a low-priority issue for HCFA." Exhibit 40 (HHC014-0172 through HHC014-0176) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

### **OBJECTION TO RFA #40:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "40", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on



the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "40" is a public document that speaks for itself, in the entirety of the document referenced in RFA #40. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "40", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #40:**

Subject to the above objections, the United States admits that the language quoted in sentence 1 is contained in Exhibit 40, though quoted out of context, and the United States admits sentence 2 of this RFA. Qualifying further, Exhibit 40 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "40", however, the United States does not admit that the words or statements contained in Exhibit "40" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**41. In 1997, HCFA's Grace Witles, Health Insurance Specialist, Bureau of Policy Development, wrote a letter to Senator Joe Lieberman that stated: "The Office of the Inspector General has issued several reports indicating that, on average, Medicare pays approximately 15 percent above the cost of drugs. In some individual cases this mark-up is much higher. We believe that the program is intended to pay physicians for their professional services and expertise, and not to pay a profit on the drugs they furnish. While in the past the program's payment for drugs may have included the cost of wastage and storage, etc., that will no longer be true." Exhibit 41 (HHC003-0507 through HHC003-0508) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #41:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA

improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "41", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document that on its face appears to be an unsigned draft. The United States states that Exhibit "41" is a public document that speaks for itself, in the entirety of the document referenced in RFA #41. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "41", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #41:**

Subject to the above objections, the United States admits that the language quoted in sentence 1 is contained in Exhibit 41, though quoted out of context and from what appears on its face to be an unsigned draft of a proposed letter. The United States admits sentences 2 and 3 of this RFA. Qualifying further, Exhibit 41 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "41", however, the United States does not admit that the words or statements contained in Exhibit "41" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA..

**42. On Jan. 21, 1997 HHS-OIG issued a report, titled Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Missouri Department of Social Services, which stated: "[W]e determined that there is a significant difference between AWP and pharmacy acquisition costs." Referring to a June 10, 1996 Barron's Magazine article, the report stated: "Barron's compared about 300 dose forms of the top 20 Medicare drugs and concluded that the true cost was 10 to 20 percent below AWP for brand**

**name drugs and 60 to 85 percent below AWP for generic drugs. Barron's also reported that industry insiders joke that AWP really means 'Ain't What's Paid.' Exhibit 42 is a true and accurate copy of this report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #42:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "42", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 4 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "42" is a public document that speaks for itself, in the entirety of the document referenced in RFA #42. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "42", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #42:**

Subject to the above objections, the United States admits only that the following language is contained in Exhibit "42": "Based on our review, we have determined that there is a significant difference between AWP and pharmacy acquisition costs". Qualifying further, Exhibit 42 speaks for itself. With respect to Exhibit "42" attached to the RFAs, all other statements are denied.

By making the qualified admissions herein concerning the content of Exhibit "42", however, the United States does not admit that the words or statements contained in Exhibit "42" represent any other position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly

admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**43. On May 29, 1997, HCFA's Adrienne M. Kaylor, Health Insurance Specialist, Bureau of Policy Development, informed Senator Russell Feingold that a proposal in the 1998 budget bill would require that Medicare "pay for drugs based on the physician's or supplier's acquisition cost for the drug. In this way, the program would pay the price charged to the physician or supplier and eliminating any markup." Exhibit 43 (HHC003-0498 through HHC003-0502) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #43:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "43", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "43" is a public document that speaks for itself, in the entirety of the document referenced in RFA #43. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "43", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #43:**

Subject to the above objections, admitted as to sentences 1, 2 and 3 with the qualifications that the letter concerned a proposal and not actual passed legislation. Moreover, this RFA misquotes the cited language. The proper quotation is: " Under the President's proposal, the program would pay for drugs based on the physician's or supplier's acquisition cost for the

drug. In this way, the program would pay the price charged to the physician or supplier and eliminate any markup." Qualifying further, Exhibit 43 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "43", however, the United States does not admit that the words or statements contained in Exhibit "43" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**44. On June 11, 1997 a member of the Virginia Carrier's Advisory Committee wrote a letter to HCFA that stated: "Instead of being reimbursed by Medicare for the actual cost, the acquisition price, [physicians] receive a far larger sum based on [AWP]. The difference between the two prices, which can be considerable, is kept by the purchaser." Exhibit 44 (HHC003-0514 through HHC003-0515) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #44:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning the member of the Virginia Carrier's Advisory Committee who created the document, it would be unduly burdensome to the United States to research and determine whether the letter attached as Exhibit "44" was made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "44", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "44" is a public document that speaks for itself, in the entirety of the document referenced in RFA #44. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to

the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "44", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial. Finally, the extraneous writing on the top of Exhibit 44 renders it impossible to verify as being a true and correct copy of the letter actually sent.

#### **RESPONSE TO RFA #44:**

Subject to the above objections, admitted as to sentence 1 with the qualification that the quoted language is taken out of context and that Exhibit 44 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "44", however, the United States does not admit that the words or statements contained in Exhibit "44" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**45. A June 24, 1997 House Committee Report accompanying the Balanced Budget Act of 1997 stated: "The Inspector General for the Department of Health and Human Services has found evidence that over the past several years Medicare has paid significantly more for drugs and biologicals than physicians and pharmacists pay to acquire such pharmaceuticals. For example, the Office of the Inspector General reports that Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs." H.R.Rep. No.105-149, at 1354. Exhibit 45 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #45:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning the member of the House Committee or staff member who created the document, it would be unduly burdensome to the United States to research and determine whether the report attached as Exhibit "45" was made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the



United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "45", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "45" is a public document that speaks for itself, in the entirety of the document referenced in RFA #45. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "45", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #45:**

Subject to the above objections, admitted as to sentences 1 and 2 with the qualification that the quoted language in sentence 1 is taken out of context. Qualifying further, Exhibit 45 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "45", however, the United States does not admit that the words or statements contained in Exhibit "45" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**46. In the legislative history to the 1997 BBA, a House Report stated that HHS-OIG reports had found that "Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs." H. Rep. No. 105-149 at 1354 (1997). Exhibit 46 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #46:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning the member of the House Committee or staff member who created the document, it would be unduly burdensome to the United States to research and determine whether the report attached as Exhibit "46" was made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "46", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "46" is a public document that speaks for itself, in the entirety of the document referenced in RFA #46. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "46", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #46:**

Subject to the above objections, admitted as to sentences 1 and 2 with the qualification that the quoted language in sentence 1 is taken out of context. Qualifying further, Exhibit 46 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "46", however, the United States does not admit that the words or statements contained in Exhibit "46" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**47. In a written response to a question posed by Senator Orrin Hatch during deliberations on the 1997 BBA, Secretary Donna Shalala stated: "Medicare pays**

**the [AWP] for covered drugs. However, the AWP is not the average price actually charged by wholesalers to their customers. Rather, it is a 'sticker' price set by drug manufacturers and published in several commercial catalogs." Hearing on President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid, and Welfare Before the Senate Committee on Finance, 105th Cong. 265 (1997) (written response of Secretary Donna Shalala to questions of Senator Hatch). Exhibit 47 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #47:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "47", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "47" is a public document that speaks for itself, in the entirety of the document referenced in RFA #47. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "47", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #47:**

Subject to the above objections, admitted as to sentences 1 and 2 with the qualification that the quoted language in sentence 1 is taken out of context. Qualifying further, Exhibit 47 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "47", however, the United States does not admit that the words or statements contained in Exhibit "47" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**48. An October 1, 1997 internal HHS memorandum from Nancy-Ann Min DePerle, HCFA Deputy Administrator, to June Gibbs Brown, Inspector General, stated that an HHS-OIG report concluded: "The published AWP's currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices which are available to the physician and supplier communities that bill for these drugs." Exhibit 48 (AWP019-1277 through AWP019-1278) is a true and accurate copy of that memorandum. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the memorandum, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #48:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "48", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "48" is a public document that speaks for itself, in the entirety of the document referenced in RFA #48. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "48", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #48:**

Subject to the above objections, admitted with the qualification that the quoted language is taken out of context. Qualifying further, Exhibit 48 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "48", however, the United States does not admit that the words or statements contained in Exhibit "48" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**49. Congressman Pete Stark wrote HHS on December 8, 1997 and stated: "The Administration should be congratulated for trying to achieve these savings in this year's budget bill. Unfortunately, because of aggressive, shameless lobbying Congress defeated the Administration's actual acquisition cost (AAC) proposal and you were presented with a continuation of the worthless average wholesale price system." Exhibit 49 (HHC001-0365 through HCC001-0366) is a true and accurate copy of Mr. Stark's letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #49:**

Without questioning Congressman Stark or his staff member who created the document, it would be unduly burdensome to the United States to research and determine whether the document attached as Exhibit "49" was made by a person with knowledge of the contents of the memorandum. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "49", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "49" is a public document that speaks for itself, in the entirety of the document referenced in RFA #49. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "49", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #49:**

Subject to the above objections, admitted as to sentences 1 and 2 with the qualification that the quoted language in sentence 1 is taken out of context and contains minor typographical capitalization misquotations. Qualifying further, Exhibit 49 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "49", however, the United States does not admit that the words or statements contained in Exhibit "49" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**50. Following passage of the 1997 BBA, President Clinton stated in a radio address to the nation: "Sometimes the waste and abuses aren't even illegal; they're just embedded in the practices of the system. These overpayments occur because Medicare reimburses doctors according to the published average wholesale price—the so-called sticker price—for the drugs. Few doctors, however, actually pay the full sticker price." White House Office of Press Secretary, Remarks by the President in Radio Address to the Nation, 1997 WL 767416 (White House Dec. 13, 1997). Exhibit 50 is a true and accurate copy of President Clinton's remarks. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #50:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "50", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the



document. The United States states that Exhibit "50" is a public document that speaks for itself, in the entirety of the document referenced in RFA #50. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "50", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #50:**

Subject to the above objections, admitted as to sentences 1 and 2 with the qualification that the language quoted in sentence 1 is misquoted and taken out of context. The correct quotation from the context of the full paragraph is: "But we must do more. Sometimes the waste and abuses aren't even illegal; they're just embedded in the practices of the system. Last week, the Department of Health and Human Services confirmed that our Medicare program has been systematically overpaying doctors and clinics for prescription drugs – overpayments that cost taxpayers hundreds of millions of dollars. Such waste is unacceptable. Now, these overpayments occur because Medicare reimburses doctors according to the published average wholesale price—the so-called sticker price—for drugs. Few doctors, however, actually pay the full sticker price. In fact, some pay just one tenth of the published price." Qualifying further, Exhibit 50 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "50", however, the United States does not admit that the words or statements contained in Exhibit "50" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**51. A December 1997 HHS-OIG report, titled Excessive Medicare Payments For Prescription Drugs, stated: "Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers." It also stated that, "[for some drug codes, the differences in allowed amounts were significant" and that "variations would seem to be caused by carriers' decisions regarding when to update reimbursement, what sources to use for documenting AWP, and in the case of multiple-source drugs, which generic drugs to include in calculating the median statistic." The report stated further that its findings "provide evidence that Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWP that are currently being used by Medicare-contracted carriers to determine reimbursement bear little**

**or no resemblance to actual wholesale prices that are available to the physicians and supplier communities that bill for drugs." Exhibit 51 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #51:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "51", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 5 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "51" is a public document that speaks for itself, in the entirety of the document referenced in RFA #51. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "51", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #51:**

Subject to the above objections, admitted with the qualification that the language quoted in sentence 1, 2 and 3 is misquoted and taken out of context. In some instances, the quotations omit several intervening paragraphs in their entirety, as well as omitting certain introductory or conclusory phrases to the partially quoted sentences set forth in RFA #51. Qualifying further, Exhibit 51 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "51", however, the United States does not admit that the words or statements contained in Exhibit "51" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any

other admission or qualification concerning the subject matter of this exhibit or RFA.

**52. On March 3, 1998, in a hearing before the House Subcommittee on Health of the Committee on Ways and Means, Congressman Pete Stark stated: "[D]octors [are] opposing the President's proposal for paying for drugs on the basis of acquisition cost rather than on this so-called average wholesale price which is sort of the equivalent of the sticker price on an automobile. If you know anybody who paid that for their car, you found somebody to sell a bridge to. These drugs are reimbursed by Medicare at 10 times the amount the doctor pays for them." Reports Regarding Medicare Payment Policies: Hearing Before the Committee on Ways and Means, 105th Cong. 31 (1998) (statement of Rep. Stark, Member, Subcomm. on Health) at 31. Exhibit 52 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #52:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning the House Committee staff who created the transcript of the Committee, it would be unduly burdensome to the United States to research and determine whether the testimony attached as Exhibit "52" was made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "52", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "52" is a public document that speaks for itself, in the entirety of the document referenced in RFA #52. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "52", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial

effect, and any other objections that may arise depending upon how it is presented at trial.

## **RESPONSE TO RFA #52:**

Subject to the above objections, the United States admits only that the following quoted language, which was misquoted in the RFA, is contained in Exhibit "52": "As she knows, [sic] have been somewhere reminding and pestering her, about doctors' opposing the President's proposal for paying for drugs on the basis of acquisition cost rather than on this so-called average wholesale price which is sort of the equivalent of the sticker price on an automobile. If you know anybody who paid that for their car, you found somebody to sell a bridge to. These drugs are reimbursed by Medicare at 10 times the amount the doctor pays for them." Qualifying further, Exhibit 52 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "52", however, the United States does not admit that the words or statements contained in Exhibit "52" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**53. On October 9, 1998, Rep. Harold Ford, Jr. (D-Tn) inserted into the Congressional Record a report that stated: "The best publicly available indicator [sic] of the prices companies charge their most favored customers, such as large insurance companies and HMOs, is the Federal Supply Schedule (FSS). The FSS is a price catalog containing goods available for purchase by federal agencies. Drug prices on the FSS are negotiated by the [VA]. The prices on the FSS closely approximate the prices that the drug companies charge their most favored non-federal customers. According to the [GAO], '[u]nder [General Services Administration] procurement regulations, VA contract officers are required to seek an FSS price that represents the same discount off a drug's list price that the manufacturer offers its most-favored non-federal customer under comparable terms and conditions.'" Prescription Drug Pricing in the 9th Congressional District in Tennessee: Drug Companies Profit At The Expense of Older Americans, 144 Cong. Rec. E2063 (October 11, 1998) (report submitted by Rep. Ford) (emphasis in original). Also on October 9, 1998, Rep. Ford submitted into the Congressional Record results related to a pricing study performed in his district. The study indicated that differences between retail prices and prices for favored customers for the top 10 drugs for senior citizens ranged from 76% to 258%, with an average differential of 115%. Rep. Ford stated that local pharmacies "appear to have relatively small markups between the prices at which they buy prescription drugs and the prices at which they sell them. The retail prices in Tennessee are 8% above**

**the published national Average Wholesale Price. The differential between retail prices and a second indicator of pharmacy costs, the prices from one wholesaler, is only 27%." 144 Cong. Rec. E2061, E2062 (daily ed. Oct. 9, 1998) (reported submitted by Rep. Ford). Exhibit 53 is a true and accurate copy of these statements. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #53:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning the Congressional staff member who created the insert into the Congressional Record, it would be unduly burdensome to the United States to research and determine whether the testimony attached as Exhibit "53" was made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "53", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "53" is a public document that speaks for itself, in the entirety of the document referenced in RFA #53. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "53", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #53:**

Subject to the above objections, admitted as to sentences 1 and 2, with the qualification that this RFA paraphrases improperly Exhibit 53 with a subjective interpretation of the content of the documents, which cannot be factually admitted. Qualifying further, Exhibit 53 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "53", however, the United States does not admit that the words or statements contained in Exhibit "53" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**54. HCFA employee Fay Baier stated in an email in 1998: "If the situation is anything like the cancer drugs, the urologists will purchase the drug for pennies on the dollar and then bill Medicare the full allowed amount; this can be quite lucrative." Exhibit 54 (HHC908-1266) is a true and accurate copy of that email. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the email, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #54:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "54", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "54" is a document that speaks for itself, in the entirety of the document referenced in RFA #54. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "54", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.



#### **RESPONSE TO RFA #54:**

Subject to the above objections, that United States admits sentences 1 to the extent that the quoted language in contained in Exhibit "54", and sentences 2 and 3. Qualifying further, Exhibit 54 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "54", however, the United States does not admit that the words or statements contained in Exhibit "54" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**55. On April 21, 1999, Congressman Pete Stark (D-Cal) wrote a letter to Nancy-Ann Min DeParle, the Administrator of HCFA. In that letter, Congressman Stark strongly urged HCFA to immediately issue written guidance to State Medicaid Programs and Medicare Carriers to approve the use of new pricing information from First Data Bank relating to certain injection, infusion and inhalation drugs and biologicals. The new pricing information was developed in connection with DOJ, HHS-OIG, HCFA, and NAMFCU. Congressman Stark stated that every day HCFA waited to implement the new pricing information, Medicare and Medicaid wasted more money in reimbursing drugs. Exhibit 55 (HHC001-0733 through HHC001-0734) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #55:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

Without questioning Congressman Stark or his staff member who created the document, it would be unduly burdensome to the United States to research and determine whether the document attached as Exhibit "55" was made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "55", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 5 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott

exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "55" is a public document that speaks for itself, in the entirety of the document referenced in RFA #55. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "55", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #55:**

Subject to the above objections, admitted only as to sentences 1 and 2, with the qualification that sentence 1 of this RFA paraphrases improperly Exhibit 55 with a subjective interpretation of the content of the documents, which cannot be factually admitted. Qualifying further, Exhibit 55 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "55", however, the United States does not admit that the words or statements contained in Exhibit "55" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**56. Exhibit 56 (HHC902-0801 through HHC902-0818) is a true and accurate copy of a report submitted to Congress by Donna Shalala, the Secretary of HHS on or about July 1, 1999. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the report, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #56:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "56", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 2 Requests for

Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States states that Exhibit "56" is a public document that speaks for itself, in the entirety of the document referenced in RFA #56. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "56", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #56:**

Subject to the above objections, admitted with the qualification that Exhibit 56 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "56", however, the United States does not admit that the words or statements contained in Exhibit "56" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**57. On June 15, 1999, in an extension of his remarks regarding the proposed Medicare Early Access Act, Rep. Pete Stark stated that the act provided for "Medicare payment for pharmaceuticals, biologicals, or parenteral nutrients on the basis of actual acquisition cost rather than the average wholesale price which is often far above the price at which the drug can really be purchased." 145 Cong. Rec. E1251, E1252 (daily ed. June 15, 1999) (statement of Rep. Stark). Exhibit 57 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #57:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning Congressman Stark or his staff member who created the document, it would be unduly burdensome to the United States to research and determine whether the

statement attached as Exhibit "57" was made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "57", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "57" is a public document that speaks for itself, in the entirety of the document referenced in RFA #57. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "57," including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #57:**

Subject to the above objections, admitted as to sentences 1 and 2 with the qualification that Exhibit "57" speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "57", however, the United States does not admit that the words or statements contained in Exhibit "57" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**58. In an email sent on October 5, 1999, CMS Region VI employee Margaret Cano stated: "In my conversation with one of the consultants from Myers and Stauffer, (Allen) he told me that the cost of the drugs given to him did not include the discounts which were received by the pharmacies. He also stated that the 17.3% discount shown for the AWP was only an average, that in reality there were much larger discounts received by some of the pharmacies. The old formula used by Arkansas rendered almost 100% profit." Exhibit 58 (HHC010-0834) is a true and accurate copy of that email. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the email,**

**and was made and kept in the course of regularly conducted business activity.**

**OBJECTION TO RFA #58:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "58", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "58" is a document that speaks for itself, in the entirety of the document referenced in RFA #58. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "58", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

**RESPONSE TO RFA #58:**

Subject to the above objection, the United States admits sentences 2 and 3 with qualification. With respect to sentence 1, the United States admits on that the quoted hearsay statements of a third party are contained in Exhibit "58". Qualifying further, Exhibit 58 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "58", however, the United States does not admit that the words or statements contained in Exhibit "58" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**59. On May 31, 2000, HHS Secretary Donna Shalala sent a letter to Hon.**

**Thomas Bliley, Chairman of the House Commerce Committee stating: "Based on our recent discussions with the Department of Justice and HHS Inspector General, we believe that the Administration's original approach—to base Medicare's payment for drugs on the physician's actual acquisition costs, perhaps adjusted for a reasonable handling fee—is probably the most effective means to ensure that Medicare is paying fairly. As part of this effort, we plan to work with physician groups to review physicians' ability to provide acquisition cost data, and to review payment rates for chemotherapy administration to ensure that they are adequate as we reduce payments for the drugs themselves to the prices that physicians pay." Exhibit 59 (AWP010-0029 through AWP010-0032) is a true and accurate copy of that letter. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #59:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "59", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "59" is a document that speaks for itself, in the entirety of the document referenced in RFA #59. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "59", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #59:**

Subject to the above objection, admitted with the qualification that Exhibit 59 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "59",



however, the United States does not admit that the words or statements contained in Exhibit "59" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**60. On June 13, 2000, Nancy-Ann Min DeParle, Administrator, U.S. Department of Health and Human Services, made the following comment to the House Committee on Ways and Means: "[T]he President has for the last four or 5 years now proposed a law to help us to be able to do this better, to make sure that we get the prices that physicians actually are paying." She was asked by Rep. Lloyd Doggett (D-Tex): "What you are saying is that there have been I believe four occasions when the administration has come to the Republican Congress and said please give us the tools to ensure that the taxpayer is not being ripped off and that they are paying the actual wholesale price and not some contrived wholesale price." In response, Ms. Min DeParle stated: "Unfortunately, yes, that is the case." Legislation to Cover Prescription Drugs Under Medicare: Hearing Before the Committee on Ways and Means, 106th Cong. 103 (2000) (statements of Nancy-Ann Min DeParle, Administrator, U.S. Department of Health and Human Services and Rep. Doggett). Exhibit 60 is a true and accurate copy of these statements. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #60:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "60", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 5 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "60" is a public document that speaks for itself,

in the entirety of the document referenced in RFA #60. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "60", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #60:**

Subject to the above objections, admitted with qualification as to sentences 4 and 5. The United States admits that Sentences 1, 2 and 3 each selectively quote language from Exhibit 60, which speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "60", however, the United States does not admit that the words or statements contained in Exhibit "60" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**61. Shortly after Secretary Donna Shalala's May 2000 announcement of a plan to equate AWP with prices actually paid by physicians, 89 Members of Congress wrote her and stated: "These data do not take into account the fact that oncologists are chronically underpaid for their drug administration services in treating cancer patients—a fact that is widely recognized, including in your letter announcing the plan to reduce reimbursement. If reimbursement for drugs is drastically reduced, many physicians will be unable to continue providing cancer care in their offices, and patients will be deprived of a humane, convenient, and cost-effective treatment option. It is important to recall that reimbursement for cancer drugs is an issue that has been repeatedly addressed by Congress over the past few years . . . . It is disturbing that [HHS] would now seek to circumvent those congressional actions by redefining AWP." Letter from 89 Members of Congress to Donna Shalala, Secretary, HHS (July 28, 2000). Exhibit 61 is a true and accurate copy of a that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #61:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average

wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning Congressmen or their staff members who created the document, it would be unduly burdensome to the United States to research and determine whether the document attached as Exhibit "61" was made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "61", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "61" is a public document that speaks for itself, in the entirety of the document referenced in RFA #61. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "61", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #61:**

Subject to the above objection, admits sentence 2, and, with qualification that the selective quotation in sentence 1 of RFA #61 is accurate through out of context from Exhibit 61, which speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "61", however, the United States does not admit that the words or statements contained in Exhibit "61" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, or any response by Congress to any position of CMS.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**62. On September 5, 2000, Senator John Ashcroft stated in the U.S. Senate: "While there are indications that drug reimbursements have often exceeded doctors' and hospitals' costs, these margins have been used to help cover costs for professional services, which are inadequately reimbursed according to the cancer**

**community, the General Accounting Office, and HCFA itself." 146 Cong. Rec. S8022, S8022 (daily ed. Sept. 5, 2000) (statement of Sen. Ashcroft). Exhibit 62 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #62:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning General Ashcroft or his Senate staff member(s) who created the document, it would be unduly burdensome to the United States to research and determine whether the remarks attached as Exhibit "62" were made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "62", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "62" is a public document that speaks for itself, in the entirety of the document referenced in RFA #62. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "62", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #62:**

Subject to the above objections, admitted with the qualification that Exhibit 62 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "62", however, the United States does not admit that the words or statements contained in Exhibit "62" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003 or any response by Congress to any CMS

position.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**63. On September 25, 2000, Representative McHugh submitted into the Congressional Record a July 2, 2000 article by journalist Alan Emory. This article stated, in part: "Letters to Congress have stressed that oncologists deserve an increase above that price, not a reduction, and they point out that many hospitals and doctors cannot obtain the needed drugs at those prices. This is not the story of greedy drug manufacturers boosting prices to the point where some Americans travel to Canada to obtain medication at reasonable prices. It is not the story of doctors and hospitals pocketing huge markups. It is one about a reduction in compensation for doctors that may be cut even more to a point where the welfare of senior citizen cancer patients is endangered." 146 Cong. Rec. E1587, E1587 (daily ed. Sept. 25, 2000) (Watertown Daily Times news article by Rep. McHugh). Exhibit 63 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #63:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning Alan Emory or his sources or his staff who created the document, it would be unduly burdensome to the United States to research and determine whether the article attached as Exhibit "63" was made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "63", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 4 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "63" is a public document that speaks for itself, in the entirety of the document referenced in RFA #63. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to

the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "63", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #63:**

Subject to the above objections, sentence 2 of RFA #63 is admitted, and the United States admits that the quoted language contained in sentence 1 of this RFA is contained in Exhibit 63, which speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "63", however, the United States does not admit that the words or statements contained in Exhibit "63" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, or any response by Congress to any CMS position.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**64. On September 25, 2000, Rep. Pete Stark stated in the Congressional Record: "Medicare has delayed reducing the level of reimbursement for various chemotherapy drugs, because of lobbying by some oncologists and drug companies that the profits are essential to cover the cost of running an oncology medical practice." 146 Cong. Rec. E1578, E1578 (daily ed. Sept. 25, 2000) (statement of Rep. Stark). Exhibit 64 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #64:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning Congressman Stark or his staff member who created the statement or the stenographer who created the Congressional Record, it would be unduly burdensome to the United States to research and determine whether the statement attached as Exhibit "64" was made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the United States has to this document, or the content



therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "49", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "64" is a public document that speaks for itself, in the entirety of the document referenced in RFA #64. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "64", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #64:**

Subject to the above objections, sentence 2 of RFA #64 is admitted with the qualification that the quoted language contained in sentence 1 of this RFA is contained in Exhibit 64, which speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "64", however, the United States does not admit that the words or statements contained in Exhibit "64" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**65. In December 2000, Congress enacted the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"), which barred the Secretary from "directly or indirectly decreas[ing] the rates of reimbursement" for drugs covered by Part B until the Comptroller General had studied the issue of Medicare drug reimbursement. Pub. L. No. 106-554 § 429, 114 Stat. 2763 (2000). Exhibit 65 is a true and accurate copy of this part of the statute. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

### **OBJECTION TO RFA #65:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "65", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "65" is a public document that speaks for itself, in the entirety of the document referenced in RFA #65. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "65", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

### **RESPONSE TO RFA #65:**

Subject to the above objections, sentence 2 of RFA #65 is admitted, and the United States admits with qualification that the quoted language contained in sentence 1 of this RFA is contained in Exhibit 65, which speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "65", however, the United States does not admit that the words or statements contained in Exhibit "65" represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**66. In order to implement BIPA, in May 2001 HCFA issued a Program Memorandum to Intermediaries and Carriers instructing them to continue using AWP's provided in industry publications, not to use "any alternative sources of data for average wholesale prices," and to disregard the September 2000 instruction to equate AWP with actual prices paid by providers. See HCFA Transmittal Mem.**

**AB-01-66, Implementation of Medicare Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) Requirements for Payment Allowance of Drugs and Biologicals Covered by Medicare (May 3, 2001). Exhibit 66 is a true and accurate copy of that memorandum. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

**OBJECTION TO RFA #66:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "66", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "66" is a public document that speaks for itself, in the entirety of the document referenced in RFA #66. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "66", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

**RESPONSE TO RFA #66:**

Subject to the above objections, the United States admits with qualification that in May of 2001 HCFA issues a Program Memorandum to Intermediaries and Carriers attached as Exhibit 66, which document speaks for itself. The United States admits sentences 2 and 3 of RFA #66.

By making the qualified admissions herein concerning the content of Exhibit "66", however, the United States does not admit that the words or statements contained in Exhibit "66" represent any other position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003 except as set forth above.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any

other admission or qualification concerning the subject matter of this exhibit or RFA.

**67. After Congress passed BIPA, HCFA Acting Administrator Michael M. Hash wrote a letter dated November 15, 2000 to Representative Tom Bliley of the Commerce Committee of the U.S. House of Representatives. In that letter, Mr. Hash commented that BIPA's freeze on the use of new AWP information from the United States Department of Justice "is a continuation of congressional efforts over the past several years to block Administration initiatives to lower drug prices." Exhibit 67 (HHC001-0357 through HHC001-0358) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #67:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "67", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "67" is a public document that speaks for itself, in the entirety of the document referenced in RFA #67. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "67", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #67:**

Subject to the above objections, the United States admits with qualification sentences 1, 3 and 4. The United States admits with the qualification that this RFA paraphrases Exhibit 67 with a subjective interpretation of the content of the documents, which cannot be factually admitted

and qualifies that Exhibit 67 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "67", however, the United States does not admit that the words or statements contained in Exhibit "67" represent any other position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, except as set forth on the face of Exhibit "67".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**68. On November 26, 2001, Minnesota Medicaid official Cody Wiberg sent an email to various parties in response to a proposal by the President of the National Community Pharmacists Association to develop a "'perfect' pharmacy reimbursement formula." Mr. Wiberg stated: "What is needed is a better method of determining actual acquisition cost (AAC). In addition to AAC, a fee should be added that takes into account the average cost of dispensing a prescription and a reasonable profit. Such a fee might have to be double what we typically pay as a dispensing fee right now." Exhibit 68 (NYSHD-FOIL 00769 through 00772) is a true and accurate copy of this email. It was made at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #68:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA improperly quotes the exhibit by taking the selected language out of context.

Without questioning Mr. Wiberg, it would be unduly burdensome to the United States to research and determine whether the e-mail attached as Exhibit "68" was made by a person with knowledge of the contents of the memorandum. Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "68", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the

document. The United States states that Exhibit "68" is a public document that speaks for itself, in the entirety of the document referenced in RFA #68. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "68", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #68:**

Subject to the above objection, sentences 2 of RFA 68 is admitted with qualification. With respect to Sentence 1, the United States admits that the quoted language is contained in Exhibit 68, which speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "68", however, the United States does not admit that the words or statements contained in Exhibit "68" by a state Medicaid official represent any position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**69. Exhibit 69 is a true and correct copy of a brief and a Statement Of Material Facts As To Which There Is No Genuine Issue, both of which were filed on or about July 10, 1991 by the Department of Health and Human Services in the U.S. District Court for the Western District of Missouri in Missouri Pharmaceutical Association, et al. v. Stangler, et al., Case No. 91-4110. Ex. 69 was made at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.**

#### **OBJECTION TO RFA #69:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

Without waiving the foregoing and any other objection that the United States has to this document, or the content therein, should Abbott elect to attempt to introduce a true, complete and correct copy of Exhibit "69", the United States will not challenge such an introduction on authenticity or genuineness grounds. The United States may, however, assert other objections to this document, including, without limitation, objections to its relevancy.

The United States objects to this request on the grounds that it contains 3 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott



exceed the total number permitted under the CMO. The United States objects to this request on the grounds that it is an improper request seeking information concerning the genuineness of the document. The United States states that Exhibit "69" is a public document that speaks for itself, in the entirety of the document referenced in RFA #69. The United States further objects on the grounds that this request seeks information that is immaterial, irrelevant and not likely to lead to the discovery of admissible evidence, and contains hearsay. The United States asserts at this time and reserves all objections to the admissibility of the document attached as Exhibit "69", including without limitation, its completeness, its relevance, its hearsay content, its prejudicial effect, and any other objections that may arise depending upon how it is presented at trial.

#### **RESPONSE TO RFA #69:**

Subject to the above objection, admitted with the qualification that Exhibit 69 speaks for itself.

By making the qualified admissions herein concerning the content of Exhibit "69", however, the United States does not admit that the words or statements contained in Exhibit "69" represent any other position by CMS, or any predecessor agency, at any time, including for the operative period of this case from 1991 until 2003, except as set forth on the face of Exhibit "69".

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

#### **Additional Requests for Admission**

**70. Between 1991 and 1997, HCFA interpreted the term "average wholesale price" or "AWP" to mean drug prices published in national compendia such as the Red Book or Blue Book.**

#### **OBJECTION TO RFA #70:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Further, the United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004).

**RESPONSE TO RFA #70:**

Subject to the above objections, denied.

**71. Ven-A-Care did not have "direct and independent knowledge" of the information upon which the allegations relating to Abbott in the 1995 complaint are based.**

**OBJECTION TO RFA #71:**

The United States objects to the RFA at not being properly directed to the correct party. The United States cannot admit or deny facts on Ven-A-Care's behalf. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

**RESPONSE TO RFA #71:**

The United States stands on its objections.

**72. Before the effective date of the Balanced Budget Act of 1997, no federal statute or regulation required Medicare Part B to provide payment to Providers based on or in any way using AWP.**

**OBJECTION TO RFA #72:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Furthermore, RFA #72 inappropriately asks the United States to admit to a legal conclusion. Moreover, even if RFA #72 did not ask for a legal conclusion, the Balanced Budget Act of 1997 is a broad statute which mentions "effective date" more than 200 times. Accordingly, RFA #72 is impossible to answer as it is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #72:**

The United States stands on its objections.

**73. After the effective date of the Balanced Budget Act of 1997, no federal statute or regulation required Medicare Part B to provide payment to Providers based on or in any way using AWP.**

**OBJECTION TO RFA #73:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Furthermore, RFA #73 inappropriately asks the United States to admit to a legal conclusion. Moreover, even if RFA #73 did not ask for a legal conclusion, the Balanced Budget Act of 1997 is a broad statute which mentions "effective date" more than 200 times. Accordingly, RFA #73 is impossible to answer as it is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #73:**

The United States stands on its objections.

**74. After the effective date of the Balanced Budget Act of 1997, one or more federal statutes or regulations did require Medicare Part B to provide payment to Providers based on or using AWP.**

**OBJECTION TO RFA #74:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Furthermore, RFA #74 inappropriately asks the United States to admit to a legal conclusion. Moreover, even if RFA #74 did not ask for a legal conclusion, the Balanced Budget Act of 1997 is a broad statute which mentions "effective date" more than 200 times. Accordingly, RFA #74 is impossible to answer as it is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #74:**

The United States stands on its objections.

**75. During the entire Relevant Claim Period, no federal statute or regulation required Medicaid to provide payment to Providers based on or in any way using**

**AWP.**

**OBJECTION TO RFA #75:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Furthermore, RFA #72 inappropriately asks the United States to admit to a legal conclusion. Accordingly, RFA #72 is impossible to answer as it is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #75:**

The United States stands on its objections.

**76. During the entire Relevant Claim Period, no federal statute or regulation prohibited Medicare Part B from providing payment to Providers at the amount that Providers paid to acquire drugs.**

**OBJECTION TO RFA #76:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #76 inappropriately asks the United States to admit to a legal conclusion. Accordingly, RFA #76 is impossible to answer as it is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #76:**

The United States stands on its objections.

**77. During the entire Relevant Claim Period, the U.S. Government had authority to seek information from Providers about their acquisition costs for the Subject Drugs.**

#### **OBJECTION TO RFA #77:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #77 calls for a legal conclusion. Moreover, RFA #77 is objectionable on the grounds that the terms Providers and the U.S. Government are vague and ambiguous. The U.S. Government incorporates three branches of government, including an Executive Branch which is further divided into multiple agencies with varying authority, subject to U.S. Congressional oversight.

#### **RESPONSE TO RFA #77:**

The United States stands on its objections.

**78. During the entire Relevant Claim Period, CMS had the authority to require Providers to indicate their actual acquisition cost for drugs on the claim forms submitted for payment by Medicare Part B.**

#### **OBJECTION TO RFA #78:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #77 calls for a legal conclusion and statutory construction and is improper. Moreover, RFA #77 is objectionable on the grounds that the term Providers is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

#### **RESPONSE TO RFA #78:**

The United States stands on its objections.

**79. During the entire Relevant Claim Period, Providers could have provided their actual acquisition cost for drugs on the claim forms submitted for payment under Medicare Part B.**

#### **OBJECTION TO RFA #79:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average

wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #79 calls for a legal conclusion and is improper. Moreover, RFA #79 is objectionable on the grounds that the term Providers is vague and ambiguous.

Further, the content of RFA #79 is improper insofar as it calls for the United States to admit or deny a hypothetical, speculative and argumentative contention. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

#### **RESPONSE TO RFA #79:**

The United States stands on its objections.

**80. During the entire Relevant Claim Period, CMS had the authority to require Providers to indicate their actual acquisition cost for drugs on the claim forms submitted for payment by Medicaid.**

#### **OBJECTION TO RFA #80:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #80 calls for a legal conclusion. Moreover, RFA #80 is objectionable on the grounds that the term "providers" is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

#### **RESPONSE TO RFA #80:**

The United States stands on its objections.

**81. During the entire Relevant Claim Period, Providers could have provided their actual acquisition cost for drugs on the claim forms submitted for payment under Medicaid.**

#### **OBJECTION TO RFA #81:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average



wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #81 calls for a legal conclusion and is improper. Moreover, RFA #81 is objectionable on the grounds that the term Providers is vague and ambiguous.

Further, the content of RFA #79 is improper insofar as it calls for the United States to admit or deny a hypothetical, speculative and argumentative contention. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

#### **RESPONSE TO RFA #81:**

The United States stands on its objections.

**82. From November 25, 1991 to the effective date of BBA 1997, Medicare Part B could have paid for drugs at an EAC that was not based upon or in any way related to AWP.**

#### **OBJECTION TO RFA #82:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #82 calls for a legal conclusion and is improper. Moreover, RFA #82 is objectionable on the grounds that the term Providers is vague and ambiguous. Objecting further, the form of RFA #82 is improper as it calls for a response to a hypothetical, speculative and argumentative question that does not call for an admission of a fact in this case, but rather speculation concerning "could have" possibilities not present in the case. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

#### **RESPONSE TO RFA #82:**

The United States stands on its objections.

**83. During the entire Relevant Claim Period, State Medicaid Programs could have paid for drugs at an EAC that was not based upon or in any way related to AWP.**

### **OBJECTION TO RFA #83:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #82 calls for a legal conclusion and is improper. Moreover, RFA #83 is objectionable on the grounds that the term Providers is vague and ambiguous. Objecting further, the form of RFA #82 is improper as it calls for a response to a hypothetical, speculative and argumentative question that does not call for an admission of a fact in this case, but rather speculation concerning "could have" possibilities not present in the case. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

### **RESPONSE TO RFA #83:**

The United States stands on its objections.

**84. From November 25, 1991 to the effective date of BBA 1997, Medicare Part B could have paid for drugs at an EAC determined by surveys or studies of Provider acquisition costs.**

### **OBJECTION TO RFA #84:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #84 calls for a legal conclusion and is improper. Moreover, RFA #84 is objectionable on the grounds that the term Providers is vague and ambiguous. Objecting further, the form of RFA #84 is improper as it calls for a response to a hypothetical, speculative and argumentative question that does not call for an admission of a fact in this case, but rather speculation concerning "could have" possibilities not present in the case. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

### **RESPONSE TO RFA #84:**

The United States stands on its objections.

**85. During the entire Relevant Claim Period, State Medicaid Programs could have paid for drugs at an EAC determined by surveys or studies of Provider acquisition costs.**

### **OBJECTION TO RFA #85:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #85 calls for a legal conclusion and is improper. Moreover, RFA #85 is objectionable on the grounds that the term Providers is vague and ambiguous. Objecting further, the form of RFA #85 is improper as it calls for a response to a hypothetical, speculative and argumentative question that does not call for an admission of a fact in this case, but rather speculation concerning "could have" possibilities not present in the case. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

### **RESPONSE TO RFA #85:**

The United States stands on its objections.

**86. During the Relevant Claim Period, State Medicaid Programs were encouraged by HCFA/CMS to base payment for drugs at an EAC determined by surveys or studies of Provider acquisition costs.**

### **OBJECTION TO RFA #86:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. To the extent that this RFP seeks an admission regarding a characterization of one or more documents, those documents are the best evidence of their content and no further response is required.

The terms "provider" and "encouraged" in RFA#86 are vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

### **RESPONSE TO RFA #86:**

Subject to the above objections, admitted that various State Medicaid programs have generally reimbursed for each drug based on the lowest of a) the EAC as set by the states, b) the maximum allowable cost ("MAC") set by the state Pharmaceutical Reimbursement Boards, or c) the providers' usual and customary charge. For multiple source drugs subject to a federal upper limit, states must in the aggregate not pay more than those limits. 42 C.F.R. §§ 447.331, 447.332 and 447.333 (2005).

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any

other admission or qualification concerning the subject matter of this RFA.

**87. During the entire Relevant Claim Period, no federal statute or regulation prevented Providers from seeking payment from Medicare Part B at the price they paid to acquire drugs.**

**OBJECTION TO RFA #87:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #87 calls for a legal conclusion. Moreover, RFA #87 is objectionable on the grounds that the terms Provider and "paid to acquire" is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs. Finally, this RFA requires the United States to speculate about Provider opinions about their legal obligations.

**RESPONSE TO RFA #87:**

The United States stands on its objections.

**88. During the entire Relevant Claim Period, no federal statute or regulation prevented Providers from seeking payment from Medicaid at the price they paid to acquire drugs.**

**OBJECTION TO RFA #88:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #88 inappropriately asks the United States to admit to a legal conclusion. Moreover, RFA #88 is objectionable on the grounds that the terms Provider and "paid to acquire" are vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #88:**

The United States stands on its objections.

**89. It is the Plaintiff's position that a Provider who submitted a claim for payment to Medicare Part B or Medicaid for a drug knowing it would be paid at an**

**amount that exceeded its acquisition cost submitted a false claim under the False Claim Act.**

**OBJECTION TO RFA #89:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #89 calls for a legal conclusion. Moreover, RFA #89 is objectionable on the grounds that the term Providers is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #89:**

The United States stands on its objections.

**90. It is the Plaintiff's position that a Provider who submitted a claim for payment to Medicare Part B or Medicaid for a drug knowing it would be paid at an amount that exceeded its acquisition cost did not submit a false claim under the False Claim Act.**

**OBJECTION TO RFA #90:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #90 calls for a legal conclusion. Moreover, RFA #90 is objectionable on the grounds that the term Providers is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #90:**

The United States stands on its objections.

**91. It is the Plaintiff's position that a Provider who submitted a claim for payment to Medicare Part B or Medicaid for a drug when it knew its acquisition cost for the drug was "far lower" (see Complaint, ¶ 3) than the AWP then published**

**for the drug submitted a false claim under the False Claim Act.**

**OBJECTION TO RFA #91:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #91 calls for a legal conclusion. Moreover, RFA #90 is objectionable on the grounds that the term Providers is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #91:**

The United States stands on its objections.

**92. It is the Plaintiff's position that a Provider who submitted a claim for payment to Medicare Part B or Medicaid for a drug when it knew its acquisition cost for the drug was "far lower" (see Complaint, ¶ 3) than the AWP then published for the drug did not submit a false claim under the False Claim Act.**

**OBJECTION TO RFA #92:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #92 calls for a legal conclusion. Moreover, RFA #92 is objectionable on the grounds that the term Providers is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #92:**

The United States stands on its objections.

**93. It is the Plaintiff's position that a Provider who submitted a claim for payment to Medicare Part B or Medicaid for a drug when it knew its acquisition cost for the drug was "far lower" (see Complaint, ¶ 3) than the AWP then published for the drug, and did not return the difference to the Medicare or Medicaid**



**program, submitted a false claim under the False Claim Act.**

**OBJECTION TO RFA #93:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #93 calls for a legal conclusion. Moreover, RFA #93 is objectionable on the grounds that the term Providers is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #93:**

The United States stands on its objections.

**94. For at least some of the false claims Plaintiff alleges Abbott caused to be filed, it is Plaintiff's position that the Provider who filed the claim submitted a false claim under the False Claims Act.**

**OBJECTION TO RFA #94:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

Moreover, RFA #94 is objectionable on the grounds it seeks a legal conclusion. Also, the term Provider is vague and ambiguous and is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs. The United States objects to this RFA as being cumulative of RFAs ## 89-93.

**RESPONSE TO RFA #94:**

The United States stands on its objections.

**95. For all of the false claims Plaintiff alleges Abbott caused to be filed, it is Plaintiff's position that the Provider who filed the claim submitted a false claim under the False Claims Act.**

#### **OBJECTION TO RFA #95:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

Moreover, RFA #95 is objectionable on the grounds it seeks a legal conclusion. Also, the term Provider is vague and ambiguous and is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs. The United States objects to this RFA as being cumulative of RFAs ## 89-94.

#### **RESPONSE TO RFA #95:**

The United States stands on its objections.

**96. During the Relevant Claim Period, no federal statute or regulation provided that Abbott or other Manufacturers must report prices for drugs.**

#### **OBJECTION TO RFA #96:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #96 inappropriately asks the United States to admit to a legal conclusion. Moreover, RFA #96 is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

#### **RESPONSE TO RFA #96:**

The United States stands on its objections.

**97. During the Relevant Claim Period, no federal statute or regulation defined the prices that Abbott or other Manufacturers must report to Publishers.**

#### **OBJECTION TO RFA #97:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #97 inappropriately asks the United States to admit to a legal conclusion. Moreover, RFA #97 is overbroad to the extent it relates to claims for reimbursement for drugs

other than the Subject Drugs.

**RESPONSE TO RFA #97:**

The United States stands on its objections.

**98. During the Relevant Claim Period, no federal statute or regulation defined the prices that Abbott or other Manufacturers reported to Publishers.**

**OBJECTION TO RFA #98:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #98 inappropriately asks the United States to admit to a legal conclusion. Moreover, RFA #98 is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #98:**

The United States stands on its objections.

**99. During the Relevant Claim Period, no federal statute or regulation regulated the prices that Abbott or other Manufacturers reported to Publishers.**

**OBJECTION TO RFA #99:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #99 inappropriately asks the United States to admit to a legal conclusion. Moreover, RFA #98 is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #99:**

The United States stands on its objections.

**100. During the Relevant Claim Period, no federal statute or regulation required Abbott or other Manufacturers to disclose their average sales prices to Publishers.**

**OBJECTION TO RFA #100:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #100 inappropriately asks the United States to admit to a legal conclusion. Moreover, the RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #100:**

The United States stands on its objections.

**101. During the entire Relevant Claim Period, HCFA/CMS was aware that the term "Average Wholesale Price" or "AWP" referred to figures reported by Publishers.**

**OBJECTION TO RFA #101:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

Moreover, the terms “was aware” is vague and ambiguous and the United States objects. Further the term “referred to” is ambiguous as it does not provide a point of reference as the RFA does not define who is doing the “referring” or what is meant by the term “refer” in the context of this RFA. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs. Further, the United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Finally, RFA #10 is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #101:**

The United States admits that certain drug pricing compendia published Average Wholesale Price information. Otherwise, the United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**102. During the entire Relevant Claim Period, HCFA/CMS was aware that AWP generally did not reflect discounts, rebates, and chargebacks associated with the sale of drugs by Manufacturers to wholesalers, distributors, and at least some Providers. (Throughout these requests, the word "generally" should be construed as it is used in paragraphs 35 and 50 of the Complaint.)**

**OBJECTION TO RFA #102:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

Moreover, the terms “was aware” is vague and ambiguous and the United States objects. Further the phrase “did not reflect” is vague and ambiguous. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs. Further, the United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Finally, RFA #102 is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #102:**

Subject to the above objections, the United States admits that HCFA/CMS received limited reports and information suggesting that the published AWP for certain drugs did not always reflect discounts, rebates, and chargebacks. Otherwise, the United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**103. During the Relevant Claim Period, AWP was not an adequate estimate of the acquisition price paid for drugs by the Customers (see Complaint, ¶ 3) who submitted the claims Plaintiff alleges were false.**

**OBJECTION TO RFA #103:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price.

The United States objects to this request on the grounds that it contains 2 Requests for Admission and, in part as a result, the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Objecting further the terms “adequate estimate” and “acquisition cost” are vague and ambiguous as the estimates and acquisition costs could reasonably be interpreted to incorporate all discounts. The United States also objects to the extent that this RFA seeks an admission for facts or information not in the possession of the

United States

**RESPONSE TO RFA #103:**

Subject to the above objections, the United States admits that it learned through the course of its investigation and litigation that the published AWP for the Subject Drugs did not accurately reflect acquisition costs available in the marketplace. Otherwise, the United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**104. During the Relevant Claim Period, AWP represented a list figure and did not reflect several types of discounts.**

**OBJECTION TO RFA #104:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

Moreover, the terms "represented," "list figure," and "reflect" are vague and ambiguous and the United States objects. The RFA is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #104:**

The United States stands on its objections.

**105. During the Relevant Claim Period, no federal statute or regulation required Abbott or other Manufacturers to report prices to Publishers that incorporated all discounts available to certain wholesalers, distributors, or purchasers of drugs.**

**OBJECTION TO RFA #105:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #105 inappropriately asks the United States to admit to a legal conclusion. Moreover, RFA #105 is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.



**RESPONSE TO RFA #105:**

The United States stands on its objections.

**106. During the Relevant Claim Period, no federal statute or regulation required Abbott or other Manufacturers to report prices to Publishers that incorporated all rebates available to certain wholesalers, distributors, or purchasers of drugs.**

**OBJECTION TO RFA #106:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #106 inappropriately asks the United States to admit to a legal conclusion. Moreover, RFA #106 is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #106:**

The United States stands on its objections.

**107. During the Relevant Claim Period, no federal statute or regulation required Abbott or other Manufacturers to report prices to Publishers that incorporated all chargebacks available to certain wholesalers, distributors, or purchasers of drugs.**

**OBJECTION TO RFA #107:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #107 inappropriately asks the United States to admit to a legal conclusion. Moreover, RFA #107 is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #107:**

The United States stands on its objections.

**108. During the Relevant Claim Period, no federal statute or regulation required Abbott or other Manufacturers to report prices to Publishers that incorporated all**

**discounts, rebates, and/or chargebacks available to certain wholesalers, distributors, or purchasers of drugs.**

**OBJECTION TO RFA #108:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #108 inappropriately asks the United States to admit to a legal conclusion. Moreover, RFA #108 is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #108:**

The United States stands on its objections.

**109. During the Relevant Claim Period, no federal statute or regulation prohibited Abbott or other Manufacturers from offering discounts, rebates, and or chargebacks to wholesalers, distributors, or purchases of drugs.**

**OBJECTION TO RFA #109:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

RFA #109 inappropriately asks the United States to admit to a legal conclusion. Moreover, RFA #109 is overbroad to the extent it relates to claims for reimbursement for drugs other than the Subject Drugs.

**RESPONSE TO RFA #109:**

The United States stands on its objection.

**110. During the Relevant Claim Period, Medicare Part B reimbursed for one or more units of a Subject Drug based on or in reference to the Provider's cost to acquire that drug.**

**OBJECTION TO RFA #110:**

The United States objects to this request on the grounds that the total number of Requests

for Admission sought by Abbott exceed the total number permitted under the CMO. Objecting further, the use of the phrases "one or more" and "Provider's cost" are vague and ambiguous.

**RESPONSE TO RFA #110:**

Subject to the above objections, the United States admits that between 1991 and 1997, Medicare Part B limited drug payments to the lower of the estimated acquisition cost or the national average wholesale price of a drug, and, that after 1998 paid the lesser of the supplier's actual charge or 95 percent of the national average wholesale price.

**111. During the Relevant Claim Period, at least one State Medicaid Program reimbursed for one or more units of a Subject Drug based on or in reference to the Provider's cost to acquire that drug.**

**OBJECTION TO RFA #111**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Objecting further, the use of the phrases "one or more" and "Provider's cost" are vague and ambiguous.

**RESPONSE TO RFA #111:**

Subject to the above objections, admitted that the State Medicaid Programs on limited occasions have reimbursed for drugs using the [provider's] usual and customary charges.

**112. During the Relevant Claim Period, Medicare Part B reimbursed for one or more units of a Subject Drug based on or in reference to the Provider's Usual and Customary Charges.**

**OBJECTION TO RFA #112:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Objecting further, the use of the term "Provider's" is vague and ambiguous and not reflecting a criteria referred to in any Medicare Part B regulation or statute.

**RESPONSE TO RFA #112:**

The United States stands on its objections.

**113. During the Relevant Claim Period, Medicaid reimbursed one or more units of a Subject Drug based on or in reference to the Provider's Usual and Customary Charges.**

**OBJECTION TO RFA #113:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Objecting further, the phrase “one or more” is vague and ambiguous.

**RESPONSE TO RFA #113:**

Subject to the above objections, admitted that the State Medicaid Programs on limited occasions have reimbursed for drugs using the [provider’s] usual and customary charges.

**114. During the Relevant Claim Period, the U.S. Government purchased one or more units of each of the Subject Drugs based on an amount arrived at through negotiations with Abbott.**

**OBJECTION TO RFA #114:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Further, the RFA is overbroad and burdensome to the extent that it requests admissions or denials from every single federal agency, including agencies whose claims are not at issue in this litigation. Finally, the phrase “one or more units” is vague and ambiguous.

**RESPONSE TO RFA #114:**

Subject to the above objections, the United States denies that HCFA/CMS paid for any of the Subject Drugs based on negotiations with Abbott. Otherwise, the United States stands on its objections.

**115. Throughout the Relevant Claim Period, the U.S. Government purchased Vancomycin from Abbott at a price at least ten times less than the AWP then published by First Data Bank.**

**OBJECTION TO RFA #115:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Further, the RFA is overbroad and burdensome to the extent that it requests admissions or denials from every single federal agency, including agencies whose claims are not at issue in this litigation.

**RESPONSE TO RFA #115:**

Subject to the above objections, the United States denies that the Medicare and Medicaid programs “purchased Vancomycin from Abbott at a price at least ten times less than the AWP then published by First Data Bank.” Otherwise, the United States stands on its objections.

**116. By at least the end of 1994, the U.S. Government had purchased Vancomycin from Abbott at a price at least ten times less than the AWP then published by First DataBank.**

**OBJECTION TO RFA #116:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Further, the RFA is overbroad and burdensome to the extent that it requests admissions or denials from every single federal agency, including agencies whose claims are not at issue in this litigation.

**RESPONSE TO RFA #116:**

Subject to the above objections, the United States denies that “by at least the end of 1994,” the Medicare and Medicaid programs “purchased Vancomycin from Abbott at a price at least ten times less than the AWP then published by First Data Bank.” Otherwise, the United States stands on its objections.

**117. Throughout the Relevant Claim Period, the U.S. Government purchased sodium chloride from Abbott at a price at least ten times less than the AWP then published by First DataBank.**

**OBJECTION TO RFA #117:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Further, the RFA is overbroad and burdensome to the extent that it requests admissions or denials from every

single federal agency, including agencies whose claims are not at issue in this litigation.

**RESPONSE TO RFA #117:**

Subject to the above objections, the United States denies that the Medicare and Medicaid programs “purchased sodium chloride from Abbott at a price at least ten times less than the AWP then published by First Data Bank.” Otherwise, the United States stands on its objections.

**118. By at least the end of the 1994, the U.S. Government had purchased sodium chloride from Abbott at a price at least ten times less than the AWP then published by First DataBank.**

**OBJECTION TO RFA #118:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Further, the RFA is overbroad and burdensome to the extent that it requests admissions or denials from every single federal agency, including agencies whose claims are not at issue in this litigation.

**RESPONSE TO RFA #118:**

Subject to the above objections, the United States denies that “by at least the end of 1994,” the Medicare and Medicaid programs “purchased sodium chloride from Abbott at a price at least ten times less than the AWP then published by First Data Bank.” Otherwise, the United States stands on its objections.

**119. Throughout the Relevant Claim Period, the U.S. Government purchased dextrose in water from Abbott at a price at least ten times less than the AWP then published by First DataBank.**

**OBJECTION TO RFA #119:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Further, the RFA is overbroad and burdensome to the extent that it requests admissions or denials from every single federal agency, including agencies whose claims are not at issue in this litigation.

**RESPONSE TO RFA #119:**

Subject to the above objections, the United States admits with qualification that the purchases were made by the Department of Veterans Affairs, and the statutes and regulations



governing the Federal Supply Schedule, and other statutory provisions dictated the negotiations. The Subject Drugs for which payment was made by Medicare Part B were not purchased by the government with respect to the claims in this case. However, the United States admits that the DVA, like other non-governmental Abbott customers, procured dextrose from Abbott at a price substantially less than the dextrose price published by First Data Bank, and that Abbott did not disclose those deeply discounted sales or otherwise report to HCFA/CMS that its reported AWP's were grossly inflated for dextrose.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**120. By at least the end of the 1994, the U.S. Government had purchased dextrose in water from Abbott at a price at least ten times less than the AWP then published by First DataBank.**

**OBJECTION TO RFA #120:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. RFA #120 is objectionable on the grounds that it would be unduly burdensome for the United States HCFA/CMS to identify the exact prices charged by Abbott and paid by the Department of Veterans Affairs for dextrose by at least the end of 1994.

**RESPONSE TO RFA #120:**

Subject to the above objections, the United States admits with qualification that the purchases were made by the Department of Veterans Affairs, and the statutes and regulations governing the Federal Supply Schedule, and other statutory provisions dictated the negotiations. The Subject Drugs for which payment was made by Medicare Part B were not purchased by the government with respect to the claims in this case. However, the United States admits that by at least the end of 1994, the DVA, like other non-governmental Abbott customers, procured dextrose from Abbott at a price substantially less than the dextrose prices published by First Data Bank, and that Abbott did not disclose those deeply discounted sales or otherwise report to HCFA/ CMS that its reported AWP's were grossly inflated for dextrose.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**121. Throughout the Relevant Claim Period, the U.S. Government purchased sterile water from Abbott at a price at least ten times less than the AWP then**

**published by First DataBank.**

**OBJECTION TO RFA #121:**

As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. RFA #121 is objectionable on the grounds that it would be unduly burdensome for the United States HCFA/CMS to identify the exact prices charged by Abbott and paid by the Department of Veterans Affairs during the Relevant Claims Period for sterile water.

**RESPONSE TO RFA #121:**

Subject to the above objections, the United States admits with qualification that the purchases were made by the Department of Veterans Affairs, and the statutes and regulations governing the Federal Supply Schedule, and other statutory provisions dictated the negotiations. The Subject Drugs for which payment was made by Medicare Part B were not purchased by the government with respect to the claims in this case. However, the United States admits that the DVA, like other non-governmental Abbott customers, procured sterile water from Abbott at a price substantially less than the sterile water price published by First Data Bank, and that Abbott did not disclose those deeply discounted sales or otherwise report to HCFA/ CMS that its reported AWP's were grossly inflated for sterile water.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**122. By at least the end of 1994, the U.S. Government had purchased sterile water from Abbott at a price at least ten times less than the AWP then published by First DataBank.**

**OBJECTION TO RFA #122:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. RFA #122 is objectionable on the grounds that it would be unduly burdensome for the United States HCFA/CMS to identify the exact prices charged by Abbott and paid by the Department of Veterans Affairs for sterile water by at least the end of 1994.

**RESPONSE TO RFA #122:**

Subject to the above objections, the United States admits with qualification that the purchases were made by the Department of Veterans Affairs, and the statutes and regulations governing the Federal Supply Schedule, and other statutory provisions dictated the negotiations. The Subject Drugs for which payment was made by Medicare Part B were not purchased by the government with respect to the claims in this case. However, the United States admits that by at least the end of 1994, the DVA, like other non-governmental Abbott customers, procured sterile water from Abbott at a price substantially less than the sterile prices published by First Data Bank, and that Abbott did not disclose those deeply discounted sales or otherwise report to HCFA/CMS that its reported AWP's were grossly inflated for sterile water.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**123. During the Relevant Claim Period, Plaintiff is unaware of any evidence that Abbott submitted an AWP to any Publisher for any of the Subject Drugs.**

**OBJECTION TO RFA #123:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The term "Plaintiff" is vague and ambiguous to the extent it refers to parties other than the United States.

**RESPONSE TO RFA #123:**

Subject to the above objection, the United States admits that Abbott submitted "list/catalog prices" to the drug pricing compendia that they used to generate the published Average Wholesale Price for the Subject Drugs. In addition, the United States admits that Abbott verified for the drug pricing compendia the published Average Wholesale Price for the Subject Drugs.

**124. During the Relevant Claim Period, Ven-A-Care is unaware of any evidence that Abbott submitted an AWP to any Publisher for any of the Subject Drugs.**

**OBJECTION TO RFA #124:**

This RFA is inappropriately directed to the United States.

**RESPONSE TO RFA #124:**

The United States stands on its objection.

**125. During the Relevant Claim Period, neither HCFA nor CMS relied on any statement made directly to it by Abbott in setting payment rates or methodologies under Medicare Part B for any of the Subject Drugs.**

**OBJECTION TO RFA #125:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Further, the term “statement” is vague and ambiguous.

**RESPONSE TO RFA #125:**

Subject to the above objection, admitted with the qualification that Abbott never disclosed to HCFA/CMS that the prices that it reported to the drug pricing compendia (and that HCFA/CMS relied upon to set Medicare and Medicaid drug payments) were inflated. The United States in discovery has asked Abbott to identify any such statements and, to date, Abbott has failed to do so.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**126. During the Relevant Claim Period, no Medicare Carrier relied on any statement made directly to that Medicare Carrier by Abbott in providing payment or setting payment rates or methodologies under Medicare Part B for any of the Subject Drugs.**

**OBJECTION TO RFA #126:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. Further, the terms “Medicare carriers” and “statement” are vague.

**RESPONSE TO RFA #126:**

Subject to the above objection, admitted with the qualification that Abbott never disclosed to HCFA/CMS that the prices that it reported to the drug pricing compendia (and that

the Medicare carriers relied upon to set Medicare drug payments) were inflated. The United States in discovery has asked Abbott to identify any such statements and, to date, Abbott has failed to do so.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**127. During the entire Relevant Claim Period, in connection with the Medicaid Drug Rebate Program, HCFA/CMS received data from Abbott that set forth AMPs for all of the Subject Drugs.**

**OBJECTION TO RFA #127:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

**RESPONSE TO RFA #127:**

Subject to the above objection, admitted with the qualification that the AMP was provided to HCFA/CMS for the sole purpose of calculating quarterly Medicaid drug rebates as required under 42 U.S.C. § 1396r-8. The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**128. During some part of Relevant Claim Period, in connection with the Medicaid Drug Rebate Program, HCFA/CMS received data from Abbott that set forth AMPs for all of the Subject Drugs.**

**OBJECTION TO RFA #128:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

**RESPONSE TO RFA #128:**

Subject to the above objection, admitted with the qualification that the AMP was provided to HCFA/CMS for the sole purpose of calculating quarterly Medicaid drug rebates as required under 42 U.S.C. § 1396r-8. The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in

no way provides any other admission or qualification concerning the subject matter of this RFA.

**129. Plaintiff does not contend that AMP information provided to HCFA/CMS by Abbott for any of the Subject Drugs during the Relevant Claim Period was inaccurate because it was too high.**

**OBJECTION TO RFA #129:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. The term “Plaintiff” is vague and ambiguous.

**RESPONSE TO RFA #129:**

Subject to the above objections, denied. Abbott previously corresponded with the HCFA/CMS regarding what it claimed were inaccuracies with the AMP data it provided for certain drugs, including some of the Subject Drugs.

**130. Plaintiff contends in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices paid by all wholesalers for that drug.**

**OBJECTION TO RFA #130:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price.

Moreover, this RFA is objectionable on the grounds that it calls for a legal conclusion.

**RESPONSE TO RFA #130:**

Subject to the above objections, denied.

**131. Plaintiff does not contend in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices paid by all wholesalers for that drug.**



**OBJECTION TO RFA #131:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Objecting further, the term "should have reflected" is vague and ambiguous given that the RFA does not identify where the reflection of AWP referenced is located.

Moreover, this RFA is objectionable on the grounds that it calls for a legal conclusion.

**RESPONSE TO RFA #131:**

Subject to the above objection, admitted.

**132. Plaintiff contends in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices charged by all wholesalers for that drug.**

**OBJECTION TO RFA #132:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Objecting further, the term "should have reflected" is vague and ambiguous given that the RFA does not identify where the reflection of AWP referenced is located.

Moreover, this RFA is objectionable on the grounds that it calls for a legal conclusion.

**RESPONSE TO RFA #132:**

Subject to the above objection, denied with qualification that the United States contends in the litigation that the published AWP for the Subject Drugs should have reflected the average wholesale price as that term is defined in *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 460 F.Supp.2d 277 (D. Mass. 2006)("the Court construes the statutory term according to its plain meaning and holds that AWP means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies").

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**133. Plaintiff does not contend in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices charged by all wholesalers for that drug.**

**OBJECTION TO RFA #133:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Objecting further, the term "should have reflected" is vague and ambiguous given that the RFA does not identify where the reflection of AWP referenced is located.

Moreover, this RFA is objectionable on the grounds that it calls for a legal conclusion.

**RESPONSE TO RFA #133:**

Subject to the above objection, denied with qualification that the United States contends in the litigation that the published AWP for the Subject Drugs should have reflected the average wholesale price as that term is defined in *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 460 F.Supp.2d 277 (D. Mass. 2006)("the Court construes the statutory term according to its plain meaning and holds that AWP means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies").

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**134. Plaintiff contends in this litigation that the published AWP for a Subject Drugs should have reflected the average of all prices paid by all Providers for that drug.**

**OBJECTION TO RFA #134:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Objecting further, the terms "Providers" and "should have reflected" are vague and ambiguous given that the RFA does not identify where the reflection of AWP referenced is located.

Moreover, this RFA is objectionable on the grounds that it calls for a legal conclusion.

**RESPONSE TO RFA #134:**

Subject to the above objection, denied with qualification that the United States contends in the litigation that the published AWP for the Subject Drugs should have reflected the average wholesale price as that term is defined in *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 460 F.Supp.2d 277 (D. Mass. 2006)("the Court construes the statutory term according to its plain meaning and holds that AWP means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies").

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**135. Plaintiff does not contend in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices paid by all Providers for that drug.**

**OBJECTION TO RFA #135:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Objecting further, the terms "Provider" and "should have reflected" are vague and ambiguous given that the RFA does not identify where the reflection of AWP referenced is located.

Moreover, this RFA is objectionable on the grounds that it calls for a legal conclusion.

**RESPONSE TO RFA #135:**

Subject to the above objection, denied with qualification that the United States contends in the litigation that the published AWP for the Subject Drugs should have reflected the average wholesale price as that term is defined in *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 460 F.Supp.2d 277 (D. Mass. 2006)("the Court construes the statutory term according to its plain meaning and holds that AWP means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies").

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**136. Plaintiff contends in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices paid to Abbott for that drug.**

**OBJECTION TO RFA #136:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price.

Objecting further, the term "should have reflected" is vague and ambiguous given that the RFA does not identify where the reflection of AWP referenced is located.

**RESPONSE TO RFA #136:**

Subject to the above objection, denied with qualification that the United States contends in the litigation that the published AWP for the Subject Drugs should have reflected the average wholesale price as that term is defined in *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 460 F.Supp.2d 277 (D. Mass. 2006)("the Court construes the statutory term according to its plain meaning and holds that AWP means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies").

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**137. Plaintiff does not contend in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices paid to Abbott for that drug.**

**OBJECTION TO RFA #137:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price.

Objecting further, the term "should have reflected" is vague and ambiguous given that the RFA does not identify where the reflection of AWP referenced is located.

**RESPONSE TO RFA #137:**

Subject to the above objection, denied with qualification that the United States contends in the litigation that the published AWP for the Subject Drugs should have reflected the average wholesale price as that term is defined in *In Re Pharmaceutical Industry Average Wholesale*

*Price Litigation*, 460 F.Supp.2d 277 (D. Mass. 2006)("the Court construes the statutory term according to its plain meaning and holds that AWP means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies").

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**138. Plaintiff is seeking damages in this litigation for reimbursement of Subject Drugs when the claim form submitted to Medicare by Providers contained a HCPCS Code or J Code but did not contain an NDC.**

**OBJECTION TO RFA #138:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

Objecting further, the term "Providers" is vague and ambiguous.

**RESPONSE TO RFA #138:**

Subject to the above objection, the United States admits with qualification that it is seeking damages for all false claims submitted or that were caused to be submitted by Abbott, no matter how they were coded or billed to Medicare on the HCFA 1500 form, or otherwise.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**139. Plaintiff is not seeking damages in this litigation for reimbursement of Subject Drugs when the claim form submitted to Medicare by Providers contained a HCPCS Code or J Code but did not contain an NDC.**

**OBJECTION TO RFA #139:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

Objecting further, the term "Providers" is vague and ambiguous.

**RESPONSE TO RFA #139:**

Subject to the above objection, the United States denied with qualification that it is

seeking damages for all false claims submitted or that were caused to be submitted by Abbott, no matter how they were coded or billed to Medicare on the HCFA 1500 form, or otherwise.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**140. Plaintiff is seeking damages in this litigation for reimbursement of Subject Drugs when the claim form submitted to Medicaid by Providers contained a HCPCS Code or J Code but did not contain an NDC.**

**OBJECTION TO RFA #140:**

The United States objects to this request on the grounds that the total number of Requests for Admission sought by Abbott exceed the total number permitted under the CMO.

Objecting further, the term "Providers" is vague and ambiguous.

**RESPONSE TO RFA #140:**

Subject to the above objection, the United States admits with qualification that it is seeking damages for all false claims submitted or that were caused to be submitted by Abbott, no matter how they were coded or billed to Medicaid.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**141. Plaintiff is not seeking damages in this litigation for reimbursement of Subject Drugs when the claim form submitted to Medicaid by Providers contained a HCPCS Code or J Code but did not contain an NDC.**

**OBJECTION TO RFA #141:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. Objecting further, the term "Providers" is vague and ambiguous. Moreover, this is not an appropriate RFA; rather it is a contention interrogatory.



**RESPONSE TO RFA #141:**

Subject to the above objection, the United States denies with qualification that it is seeking damages for all false claims submitted or that were caused to be submitted by Abbott, no matter how they were coded or billed to Medicaid.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**142. During the Relevant Claim Period, for purchases of drugs made pursuant to Section 340 of the federal Public Health Act, 340B Providers were required to submit their actual acquisition cost of a drug to Medicaid when seeking reimbursement of such drug.**

**OBJECTION TO RFA #142:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. This RFA seeks and admission about matters beyond the scope of the case, calls for a legal conclusion, and is irrelevant.

**RESPONSE TO RFA #142:**

The United States stands on its objections.

**143. During the Relevant Claim Period, for purchases of drugs made pursuant to Section 340 of the federal Public Health Act, 340B Providers submitted their actual acquisition cost of a drug to Medicaid when seeking reimbursement of such drug.**

**OBJECTION TO RFA #143:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. This seeks an admission about matters beyond the scope of the case, calls for a legal conclusion, and is irrelevant.

**RESPONSE TO RFA #143:**

The United States stands on its objections.

**144. As of August 15, 1975, the Secretary of HHS was aware that AWP data often was not closely related to the drug prices actually charged to and paid by Providers.**

**OBJECTION TO RFA #144:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Further, the terms "was aware," "AWP data," and "closely related" are vague and ambiguous. Further, the United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Finally, this RFA seeks an admission about matters beyond the scope of the case, is irrelevant, and is unduly burdensome.

**RESPONSE TO RFA #144:**

The United States stands on its objections.

**145. As of December 1977, HHS was not convinced that states continuing to reimburse at AWP had made a real effort to approach Provider's actual acquisition costs for drugs reimbursed by Medicaid.**

**OBJECTION TO RFA #145:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. Further, the terms "real effort to approach" and "was not convinced" are vague and ambiguous. Further, the United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Finally, this RFA seeks an admission about matters beyond the scope of the case, is irrelevant, and is unduly burdensome.

**RESPONSE TO RFA #145:**

Subject to the above objections, denied.

**146. In June 1984, HHS-OIG advised state Medicaid agencies that AWP cannot be the best—or even an adequate—estimate of the price Providers generally pay for drugs, and that it represents a list price and does not reflect several types of discounts.**

**OBJECTION TO RFA #146:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Further, the words “best,” “adequate,” or “advised” are vague and ambiguous. Finally, this RFA seeks an admission about matters beyond the scope of the case, is irrelevant, and is unduly burdensome.

**RESPONSE TO RFA #146:**

Subject to the above objections, denied.

**147. Prior to 1984, the Secretary of HHS lacked cumulative, well-documented evidence affirmatively demonstrating that AWP was in fact not an accurate measure of the prices generally paid by Providers.**

**OBJECTION TO RFA #147:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The terms “cumulative well-documented evidence,” and “affirmatively demonstrating” are vague and ambiguous. Objection, any 1984 knowledge by the Secretary of HHS is irrelevant to this case. Finally, the RFA concerns matters outside of the Relevant Period of the case or drug products that are not the subject of this case is unduly burdensome.

**RESPONSE TO RFA #147:**

The United States stands on its objections.

**148. After 1984, the Secretary of HHS was aware of a widening base of documented evidence demonstrating that AWP significantly overstated the**

**Provider's acquisition costs.**

**OBJECTION TO RFA #148:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Further, the United States objects because the terms "after 1984," "significantly overstated," and "was aware of a widening base of documented evidence" are vague and ambiguous. Also, the United States' objects to Abbott's attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Further, any knowledge by the Secretary of HHS from 1984 through 1991 is irrelevant to this case. Finally, the RFA requests an admission concerning matters outside of the Relevant Period of the case or drug products that are not the subject of this case is unduly burdensome.

**RESPONSE TO RFA #148:**

The United States stands on its objections.

**149. In or about 1984, HHS became convinced as a factual matter that there was a significant discrepancy between AWP and the actual purchase prices for drugs.**

**OBJECTION TO RFA #149:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The terms "HHS became convinced" and "significant discrepancy" are vague and ambiguous. Further, the United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Further, responding to requests for admission concerning matters outside of the Relevant Period of the case or drug products that are not the subject of this case is unduly burdensome. Finally, the RFA seeks an admission about matters that are irrelevant.

**RESPONSE TO RFA #149:**

The United States stands on its objections.

**150. In June 1984, HHS-OIG recommended that HCFA revise the upper limit regulations applicable to Medicaid drug reimbursement to include a specific prohibition on use of AWP in establishing the EAC for those drugs.**

**OBJECTION TO RFA #150:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Also, any 1984 recommendation by HHS-OIG is irrelevant to this case. RFA #150 is vague and ambiguous as it does not identify the exact content or attach the specific written HHS-OIG recommendation, which should speak for itself. Further, responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. Finally, this RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #150:**

The United States admits that HHS-OIG issued a report in 1984 proposing changes to the Medicaid prescription drug program, but denies that that report discussed any of the Subject Drugs.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this exhibit or RFA.

**151. In September 1984, HCFA believed that within the pharmaceutical industry, AWP meant undiscounted list price and that pharmacies purchased drugs at prices discounted significantly below AWP or list price.**

**OBJECTION TO RFA #151:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The term "believed" is vague and ambiguous. The RFA also attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Any purported "belief" by HHS in 1984 is irrelevant to this case. The RFA seeks an admission about irrelevant matters.. Finally, responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug

products that are not the subject of this case is unduly burdensome.

**RESPONSE TO RFA #151:**

The United States stands on its objections.

**152. In September 1984, HCFA believed that excessive payments were being made nationwide for the ingredient cost of prescription drugs under the Medicaid program.**

**OBJECTION TO RFA #152:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. The terms "believed" and "excessive payments" are vague and ambiguous. The United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Further, responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. Finally, this RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #152:**

The United States stands on its objections set forth above.

**153. In September 1984, HCFA sent the June 1984 HHS-OIG Audit Report to all state Medicaid agencies in order to make them aware of the potential savings that could result if states would make a greater effort to determine more closely the price pharmacists pay for drugs, rather than using AWP.**

**OBJECTION TO RFA #153:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Any 1984 HHS-OIG recommendation is irrelevant to this case. Responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. This RFA seeks an admission about irrelevant matters.



#### **RESPONSE TO RFA #153:**

To the extent HCFA sent any document to the state Medicaid agencies in September 1984, such document speaks for itself. Otherwise, the United States stands on its objections.

**154. As of September 17, 1985, HCFA believed that states could no longer claim to be applying their best estimates to determining prescription drug costs if they relied solely on AWP, unless they provided other evidence that supported a contrary conclusion.**

#### **OBJECTION TO RFA # 154:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The term "believed" is vague and ambiguous. Further, the United States objects to Abbott's attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. This RFA seeks an admission about irrelevant matters.

#### **RESPONSE TO RFA #154:**

The United States stands on its objections.

**155. On September 4, 1985, officials from HCFA's central office believed that states should be free to develop and adopt any method of drug pricing that resulted in a more accurate reflection of Providers' costs since no specific methodology developed at the federal level was mandated.**

#### **OBJECTION TO RFA # 155:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. Objecting further, the term "believed" is vague and ambiguous. Objection, to the extent that Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). This RFA seeks an admission concerning irrelevant drug products that are not included among the Subject Drugs. Responding to requests for admission concerning matters outside of the Relevant Period of the case or

concerning drug products that are not the subject of this case is unduly burdensome. This RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #155:**

The United States stands on its objections.

**156. As of 1987, HHS believed that published AWP's were not representative of the prices pharmacists actually paid for drugs because surveys showed that pharmacies generally purchased drugs at prices that were discounted significantly below AWP.**

**OBJECTION TO RFA # 156:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The terms "believed," "representative," and "significantly" are vague and ambiguous. The United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). This RFA seeks an admission concerning irrelevant drug products that are not included among the Subject Drugs. Responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. This RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #156:**

The United States stands on its objections.

**157. On May 16, 1988, HCFA believed there was a preponderance of evidence that AWP significantly overstated the price pharmacy Providers paid for drug products and that AWP was not the price generally and currently paid by Providers.**

**OBJECTION TO RFA # 157:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of

AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The terms "believed there was a preponderance of evidence," "significantly overstated," and "generally and currently" are vague and ambiguous. The United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. This RFA calls for a legal conclusion and is irrelevant.

#### **RESPONSE TO RFA #157:**

The United States admits that the HCFA Administrator wrote a letter on or about May 16, 1988 disapproving Louisiana's State Plan Amendment. Otherwise, the United States stands on its objections.

**158. As of May 16, 1988, the HCFA Administrator was aware that AWP significantly overstated the price pharmacy Providers actually paid for drug products.**

#### **OBJECTION TO RFA #158:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The terms "was aware", "significantly overstated" are vague and ambiguous. The United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. This RFA seeks an admission about irrelevant matters.

#### **RESPONSE TO RFA #158:**

The United States admits that the HCFA Administrator wrote a letter on or about May 16, 1988 disapproving Louisiana's State Plan Amendment. Otherwise, the United States stands on its objections.

**159. As of May 16, 1988, the continued use of AWP as the basis for reimbursing Providers under Medicaid resulted in significant overpayments to pharmacy Providers.**

**OBJECTION TO RFA # 159:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The term "significant overpayments" is vague and ambiguous. This RFA fails to specify the drugs or products referenced as being "reimbursed" to Providers. Responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. This RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #159:**

The United States admits that the HCFA Administrator wrote a letter on or about May 16, 1988 disapproving Louisiana's State Plan Amendment. Otherwise, the United States stands on its objections.

**160. In 1989, the HCFA Administrator believed that average wholesale price was significantly higher than actual costs and was somewhat comparable to the manufacturer's sticker price on a new car.**

**OBJECTION TO RFA # 160:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or "average wholesale price" as not being an accurate definition of AWP or average wholesale price. The terms "believed" and "significantly higher," and sticker price on a new car" are vague and ambiguous. The United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). This request seeks information concerning irrelevant drug products that are not included among the Subject Drugs. Responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. This RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #160:**

The United States stands on its objections.

**161. From 1989 to 1991, HCFA invalidated or threatened to invalidate state Medicaid programs in Louisiana, Arkansas, and Oklahoma that used undiscounted AWP as the benchmark for reimbursement and also refused to pay the federal share to such states. See Louisiana v. U.S. Dep't of Health & Human Servs., 905 F.2d 877 (5th Cir. 1990); In re Arkansas Dep't of Human Servs., 1991 WL 634857 (HHS Dept. App. Bd. Aug. 22, 1991); In re Oklahoma Dep't of Human Servs., 1991 WL 634860 (HHS Dept. App. Bd. Aug. 13, 1991); Rite Aid of Pa., Inc. v. Houston, 171 F.3d 842, 847 (3d Cir. 1999).**

#### **OBJECTION TO RFA #161:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA seeks an admission about irrelevant matters and for legal conclusions.

#### **RESPONSE TO RFA #161:**

Subject to the above objections, the United States admits only that the published written opinions of HCFA regarding state Medicaid programs speak for themselves in the context of the facts of the adjudicated cases.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**162. As of October 5, 1989, HCFA believed that published AWP was not an acceptable measure of estimated acquisition cost because it was frequently inflated and did not reflect the various incentives, sales promotions, discounts and allowances that were routine terms of purchasing in the drug marketplace.**

#### **OBJECTION TO RFA #162:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Objection, the terms "believed" and "not an acceptable measure" are vague and ambiguous. Objection, to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004).

Objection, responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. Objection, this RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #162:**

The United States admits that on or about October 5, 1989, HCFA wrote a letter to the Arkansas Department of Health Services. Otherwise, the United States stands on its objections

**163. As of 1990, the Secretary of HHS believed that AWP rarely, if ever, reflected the prices actually paid by pharmacies.**

**OBJECTION TO RFA #163:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The terms "believed" and "rarely" are vague and ambiguous. The United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). This RFA seeks an admission about irrelevant matters. Responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome.

**RESPONSE TO RFA #163:**

The United States stands on its objections.

**164. As of 1990, the Secretary of HHS believed that the agency's policy since 1976 had been that AWP was not an acceptable measure of estimated acquisition cost.**

**OBJECTION TO RFA #164:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The terms "believed" and "agency's policy" are vague and ambiguous. The United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to



the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. This RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #164:**

The United States stands on its objections.

**165. From 1976 to 1990, the policy of HHS was that published AWP's were not an acceptable measure of estimated acquisition cost.**

**OBJECTION TO RFA #165:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. This RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #165:**

Subject to the above objections, denied.

**166. As of January 12, 1990, the position of the Secretary of HHS was that AWP significantly overstated the prices pharmacists were generally paying for prescription drugs.**

**OBJECTION TO RFA #166:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The terms "believed" and "agency's policy" are vague and ambiguous. Responding to requests for admission concerning matters outside of the Relevant Period of the case or concerning drug products that are not the subject of this case is unduly burdensome. This RFA seeks an admission about irrelevant matters.

### **RESPONSE TO RFA #166:**

The United States admits that on or about January 12, 1990, HHS filed a brief in *The State of Louisiana v. The United States Department of Health and Human Services*, Case No. 89-4566 (5th Cir., July 13, 1990) and that that brief speaks for itself. Otherwise, the United States stands on its objections.

**167. As of October 20, 1992, HCFA was aware that the EAC of Vancocin/Vancomycin 500 ML was \$5.00 while the median AWP for the same drug was \$19.17, based on surveys of actual invoice prices at dialysis facilities during May 1991.**

### **OBJECTION TO RFA #167:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Objection, this RFA seeks an admission about matters beyond the scope of the case and is irrelevant.

### **RESPONSE TO RFA #167:**

Subject to the above objections, the United States admits with qualification only that on or about October 20, 1992, HHS-OIG issued a report based upon its examination of the invoice prices paid by approximately 30 dialysis facilities during May 1991, that the prices paid by those facilities for Vancocin/Vancomycin 500 ML covered a wide range of prices, and that the report included a chart that listed the EAC of Vancocin/Vancomycin 500 ML as \$5.00 and also listed the EAC for other drugs. However, the report did not identify whether any of the dialysis facilities were purchasing Vancocin/Vancomycin 500 ML that had been manufactured by Abbott. Thus, the report does not provide any basis upon which to conclude that the Vancocin/Vancomycin 500 ML being sold by Abbott was the basis for listing the EAC at \$5.00, or whether, for example, the vancomycin sold by Abbott was being sold at the highest price (\$26.61) shown in the invoices, or whether the vancomycin sold by Abbott was being sold at an even higher price that was not reflected in the invoices at all because none of the 30 dialysis facilities approached by HHS used the version of vancomycin manufactured by Abbott. The United States admits that the report was transmitted to HCFA but denies that information in an HHS-OIG report could be used on an *ad hoc* basis to determine the payment amount for a Medicare claim during the relevant claim period.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**168. As of March 18, 1993, HCFA and state Medicaid officials agreed that pharmacies often used excess Medicaid reimbursements to cover their dispensing costs.**

**OBJECTION TO RFA #168:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The United States objects to the extent that this RFA seeks admissions beyond official HCFA positions set forth in public documents, which speak for themselves. The terms "state Medicaid officials", who are unidentified, and "agreed" are vague and ambiguous. This RFA is overly broad. Surveying all state Medicaid officials from 1993 to ascertain which officials are at issue and what agreement, if any, ever existed would be unduly burdensome. This RFA seeks an admission about irrelevant matters. Responding to requests for admission concerning drug products that are not the subject of this case is unduly burdensome.

**RESPONSE TO RFA #168:**

The United States stands on its objections.

**169. As of March 18, 1993, HCFA believed that pharmacies often used excess Medicaid reimbursements to cover their dispensing costs.**

**OBJECTION TO RFA #169:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. This RFA seeks an admission about irrelevant matters. Responding to requests for admission concerning drug products that are not the subject of this case is unduly burdensome.

**RESPONSE TO RFA #169:**

Subject to the above objections, denied.

**170. As of 1997, the Secretary of HHS believed that AWP was not the average**

**price actually charged by wholesalers to their customers but rather a sticker price set by drug manufacturers and published in several commercial catalogs.**

**OBJECTION TO RFA #170:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price.

**RESPONSE TO RFA #170:**

Subject to the above objections, the United states admits this request with the qualification that the United States admits only what is set forth in the public record, which speaks for itself.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**171. As of October 1, 1997, the HCFA Administrator believed that the published AWP's used by Medicare carriers to determine reimbursement did not resemble the actual wholesale prices available to the physician and supplier communities that billed for such drugs.**

**OBJECTION TO RFA #171:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The term "believed" is vague and ambiguous. Objection, this RFA is overly broad. The United States objects to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). This RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #171:**

Subject to the above objections, the United States admits that statements may exist in the public record which speak for themselves.

The United States denies all other statements contained in this RFA not expressly

admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**172. As of June 13, 2000, the HCFA Administrator believed that on several occasions the administration had unsuccessfully sought from Congress the tools necessary to ensure that HCFA was paying the actual wholesale price rather than a contrived wholesale price.**

**OBJECTION TO RFA #172:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. The term "believed" is vague and ambiguous. This RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #172:**

Subject to the above objections, the United States admits that statements may exist in the public record which speak for themselves.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**173. As of November 15, 2000, the HCFA Administrator believed that the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA") was a continuation of congressional efforts to block initiatives to lower drug prices.**

**OBJECTION TO RFA #173:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. As noted in the General Objections, the United States objects to Abbott's definition of AWP or average wholesale price as not being an accurate definition of AWP or average wholesale price. Objection, the terms "believed" and "blocked" are vague and ambiguous. Objection, to the extent Abbott attempts to ascribe the views of HCFA employees to the organization as a whole. *United States v. Lachman*, 387 F.3d 42, 53-54 (1st Cir. 2004). Objection, this RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #173:**

Subject to the above objections, the United States admits that HCFA Acting Administrator Michael Hash wrote a letter dated November 15, 2000, to Representative Tom Bliley and that that letter speaks for itself.

The United States denies all other statements contained in this RFA not expressly admitted, objected to or qualified herein and submits that this response in no way provides any other admission or qualification concerning the subject matter of this RFA.

**174. The reports and regulations listed on Schedules A and B of Defendant Abbott Laboratories' First Set of Requests for Production of Documents and Tangible Things to Plaintiff United States of America are public records or reports that set forth activity of various agencies of the U.S. Government.**

**OBJECTION TO RFA #174:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. The phrase "set forth activity of various agencies of the U.S. Government" is vague and ambiguous. This RFA seeks an admission about irrelevant matters.

**RESPONSE TO RFA #174:**

The United States stands on its objections.

**175. On or about the time they were prepared, the U.S. Government distributed copies of those final reports listed on Schedule A of Defendant Abbott Laboratories' First Set of Requests for Production of Documents and Tangible Things to Plaintiff United States of America to State Medicaid directors. If the U.S. Government cannot make this admission for all of the listed reports, please list those reports listed on that Schedule A where the U.S. Government can make the admission.**

**OBJECTION TO RFA #175:**

The United States objects to this request on the grounds that the total number of requests for admission sought by Abbott exceed the total number permitted under the Case Management Order. This RFA seeks an admission about irrelevant matters. This RFA is overly burdensome.



**RESPONSE TO RFA #175:**

The United States stands on its objections.

Respectfully Submitted,

For the United States of America,

MICHAEL J. SULLIVAN  
UNITED STATES ATTORNEY

/s/ George B. Henderson, II

George B. Henderson, II  
Assistant U.S. Attorney  
John Joseph Moakley U.S. Courthouse  
Suite 9200, 1 Courthouse Way  
Boston, MA 02210  
Phone: (617) 748-3272  
Fax: (617) 748-3971

R. ALEXANDER ACOSTA  
UNITED STATES ATTORNEY  
SOUTHERN DISTRICT OF FLORIDA

/s/ Ann St. Peter-Griffith

Mark A. Lavine  
Ana Maria Martinez  
Ann St. Peter-Griffith  
Special Attorneys for the Attorney General  
99 N.E. 4th Street, 3rd Floor  
Miami, FL 33132  
Phone: (305) 961-9003  
Fax: (305) 536-4101

MICHAEL MUKASEY  
UNITED STATES ATTORNEY  
GENERAL

/s/ Gejaa T. Gobena

Daniel R. Anderson  
Renée Brooker  
Justin Draycott  
Gejaa T. Gobena  
Civil Division  
Commercial Litigation Branch  
P. O. Box 261  
Ben Franklin Station  
Washington, D.C. 20044  
Phone: (202) 307-1088  
Fax: (202) 307-3852

### **CERTIFICATE OF SERVICE**

I hereby certify that I have this day caused an electronic copy of the above UNITED STATES'S OBJECTIONS AND RESPONSES TO ABBOTT LABORATORIES, INC.'S REVISED FIRST SET OF Requests for Admission TO PLAINTIFF UNITED STATES OF AMERICA AND RELATOR VEN-A-CARE OF THE FLORIDA KEYS, INC. to be served on all counsel of record via electronic service pursuant to Paragraph 11 of CMO No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: February 11, 2008

/s/  
\_\_\_\_\_  
Justin Draycott  
Civil Division, U.S. Department of Justice